

EXHIBIT B32

Karla Ballman, Ph.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW JERSEY

- - -

IN RE: JOHNSON & :
JOHNSON TALCUM POWDER :
PRODUCTS MARKETING, :
SALES PRACTICES, AND : NO. 16-2738
PRODUCTS LIABILITY : (FLW) (LHG)
LITIGATION :
:
THIS DOCUMENT RELATES :
TO ALL CASES :

- - -

March 22, 2019

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Videotaped deposition of
KARLA BALLMAN, Ph.D., taken pursuant to
notice, was held at Skadden Arps, Four
Times Square, New York, New York,
beginning at 9:04 a.m., on the above
date, before Michelle L. Gray, a
Registered Professional Reporter,
Certified Shorthand Reporter, Certified
Realtime Reporter, and Notary Public.

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Karla Ballman, Ph.D.

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Testimony of:

KARLA BALLMAN, Ph.D.

By Mr. Tisi 13, 566

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<p style="text-align: right;">Page 11</p> <p>1 - - - 2 DEPOSITION SUPPORT INDEX 3 - - - 4 5 Direction to Witness Not to Answer 6 PAGE LINE 7 None. 8 9 Request for Production of Documents 10 PAGE LINE 11 None. 12 13 Stipulations 14 PAGE LINE 15 None. 16 17 Questions Marked 18 PAGE LINE 19 None. 20 21 22 23 24</p>	<p style="text-align: right;">Page 13</p> <p>1 - - - 2 EXAMINATION 3 - - - 4 BY MR. TISI: 5 Q. Good morning? 6 A. Good morning. 7 Q. Would you please state your 8 name. 9 A. Karla Ballman. 10 Q. And it's Karla Ballman, 11 Ph.D.? 12 A. Well, that's my degree, is a 13 Ph.D. 14 Q. Correct. You know that 15 you've been identified by Johnson & 16 Johnson lawyers as an expert in the 17 talcum powder litigation? 18 A. Yes. I've been retained by 19 Johnson & Johnson as an expert. 20 Q. Okay. At the request of 21 Johnson & Johnson's lawyers, did you 22 prepare an expert report on behalf of 23 Johnson & Johnson? 24 A. I did prepare an expert</p>

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<p style="text-align: right;">Page 14</p> <p>1 report.</p> <p>2 Q. Okay. And I'd like to have</p> <p>3 that marked as Exhibit Number 1.</p> <p>4 (Document marked for</p> <p>5 identification as Exhibit</p> <p>6 Ballman-1.)</p> <p>7 BY MR. TISI:</p> <p>8 Q. Now Dr. Ballman, does</p> <p>9 this -- does this report that you issued</p> <p>10 address the epidemiologic question about</p> <p>11 whether talcum powder products are</p> <p>12 capable of causing ovarian cancer?</p> <p>13 A. Yes. I had been asked to</p> <p>14 look at all the evidence and totality and</p> <p>15 come to -- to determine whether or not</p> <p>16 ovarian cancer -- I mean talcum powder</p> <p>17 causes ovarian cancer.</p> <p>18 Q. Okay. And you reached that</p> <p>19 to a reasonable degree of medical</p> <p>20 certainty?</p> <p>21 A. My -- my expertise is in</p> <p>22 epidemiology and statistics, and so I</p> <p>23 reached it to a reasonable degree of</p> <p>24 certainty coming from it, from an</p>	<p style="text-align: right;">Page 16</p> <p>1 This question -- this report</p> <p>2 addresses the question about whether or</p> <p>3 not, in your opinion, to a reasonable</p> <p>4 degree of certainty, that talcum powder</p> <p>5 products cause or does not cause ovarian</p> <p>6 cancer.</p> <p>7 A. Yeah. So this report</p> <p>8 describes the -- what I went through to</p> <p>9 look at the data in totality with respect</p> <p>10 to the question as to whether there is</p> <p>11 evidence to support the hypothesis that</p> <p>12 talcum powder applied to the perineum</p> <p>13 causes ovarian cancer.</p> <p>14 Q. And in fact, the cover page</p> <p>15 which you signed says "Expert Report of</p> <p>16 Karla Ballman Ph.D. for General Causation</p> <p>17 Daubert Hearing."</p> <p>18 Do you see that?</p> <p>19 A. Okay. I see that. So I</p> <p>20 didn't know what the legal terms were.</p> <p>21 So I did do this report, yes.</p> <p>22 Q. And this report is your</p> <p>23 assessment of both the epidemiologic and</p> <p>24 non-epidemiologic evidence through a</p>
<p style="text-align: right;">Page 15</p> <p>1 epidemiology standpoint. I'm not sure</p> <p>2 what you mean by medicine. I'm not an</p> <p>3 M.D.</p> <p>4 Q. Okay. What does reasonable</p> <p>5 degree of certainty mean to you?</p> <p>6 A. It means that I don't see</p> <p>7 any evidence that supports that</p> <p>8 hypothesis.</p> <p>9 Q. Okay. No evidence?</p> <p>10 A. Credible evidence.</p> <p>11 Q. The report that you issued</p> <p>12 is your epidemiologic assessment of that</p> <p>13 general causation question about whether</p> <p>14 talcum powder products is capable of</p> <p>15 causing ovarian cancer, true?</p> <p>16 A. What do you mean by general</p> <p>17 causation? I know that lawyers use</p> <p>18 different words than what I use. And</p> <p>19 they place a lot of emphasis on the words</p> <p>20 they use, like I do on the numbers. So</p> <p>21 I'm not quite sure what you mean by</p> <p>22 general causation.</p> <p>23 Q. Whether or not -- let's take</p> <p>24 the word general causation out.</p>	<p style="text-align: right;">Page 17</p> <p>1 framework that we will be talking about</p> <p>2 today called the Bradford Hill framework,</p> <p>3 correct?</p> <p>4 A. What do you mean by</p> <p>5 non-epidemiologic?</p> <p>6 Q. I think I used -- those were</p> <p>7 the words that you used in the report.</p> <p>8 A. Did I? Can you point me to</p> <p>9 the page where I used those words?</p> <p>10 Q. I'm not going to waste my</p> <p>11 time to do it. But you -- I think you</p> <p>12 talked about that you were looking at</p> <p>13 both the observational studies and the</p> <p>14 non-observational evidence?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: So as -- as an</p> <p>17 expert in epidemiology and</p> <p>18 statistics, and I do this like day</p> <p>19 in and day out, as part of my</p> <p>20 life, I look at the totality of</p> <p>21 the evidence.</p> <p>22 So some of the evidence</p> <p>23 involved human. And some of the</p> <p>24 evidence may involve some animal</p>

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<p>Page 18</p> <p>1 experiments, and some evidence I</p> <p>2 look at might involve some cell</p> <p>3 line experiments.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. And we'll talk about</p> <p>6 that. We'll talk about that for sure.</p> <p>7 In collecting that evidence</p> <p>8 did you organize your evidence</p> <p>9 considering what I think the record will</p> <p>10 reflect is the Bradford Hill framework?</p> <p>11 A. Within my report I do have</p> <p>12 sections that go through the Bradford</p> <p>13 Hill framework.</p> <p>14 Q. Okay. And you know what the</p> <p>15 Bradford Hill framework is, correct?</p> <p>16 A. I do.</p> <p>17 Q. And after collecting the</p> <p>18 evidence, did you then weigh the</p> <p>19 evidence?</p> <p>20 A. So weigh it in what respect?</p> <p>21 Q. I'm asking you, how did</p> <p>22 you -- how did you -- well, we'll come</p> <p>23 back to this.</p> <p>24 But you looked at the</p>	<p>Page 20</p> <p>1 Q. Okay. And that's your</p> <p>2 opinion?</p> <p>3 A. I just work with -- I don't</p> <p>4 think that's my opinion. I think it's</p> <p>5 the basis of what all epidemiologists put</p> <p>6 together as --</p> <p>7 Q. And so it's your opinion</p> <p>8 that all epidemiologists agree that</p> <p>9 cohort studies are better than</p> <p>10 case-control studies?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: Again, it</p> <p>13 depends. Are you saying cohort</p> <p>14 studies in general --</p> <p>15 BY MR. TISI:</p> <p>16 Q. Yes. Prospective --</p> <p>17 A. -- or are you talking</p> <p>18 about --</p> <p>19 Q. Prospective cohort studies</p> <p>20 are better than case-control studies on</p> <p>21 your hierarchy of evidence.</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: You know,</p> <p>24 again, it depends. That's a</p>
<p>Page 19</p> <p>1 evidence and you decided which evidence,</p> <p>2 if any, was credible or not, correct?</p> <p>3 A. I looked at the evidence in</p> <p>4 totality. And what I -- and I think I</p> <p>5 lay out in my report, you know, there --</p> <p>6 there is sort of a general hierarchy of</p> <p>7 epidemiologic evidence that goes from,</p> <p>8 like, lowest -- it's like a pyramid. I</p> <p>9 think it's Figure 2 in my report -- up to</p> <p>10 the highest evidence. And that's the</p> <p>11 type of weight I put on it.</p> <p>12 So, for instance, I place</p> <p>13 sort of evidence coming out of -- bless</p> <p>14 you -- cohort studies higher than</p> <p>15 evidence coming out of case-control</p> <p>16 studies.</p> <p>17 Q. Okay. And your -- and we'll</p> <p>18 talk about this. But your opinion is</p> <p>19 that cohort studies are stronger</p> <p>20 evidence, more reliable evidence than</p> <p>21 case -- case-control studies?</p> <p>22 A. I believe epidemiology,</p> <p>23 that's a fairly well established</p> <p>24 principle.</p>	<p>Page 21</p> <p>1 pretty general thing. I'm just</p> <p>2 saying that if you -- you look in</p> <p>3 epidemiology textbooks, if you</p> <p>4 look in any other places where</p> <p>5 this is discussed, cohort studies</p> <p>6 as a whole in general are placed</p> <p>7 higher than the evidence coming</p> <p>8 out of case-control studies.</p> <p>9 BY MR. TISI:</p> <p>10 Q. And we'll talk about that.</p> <p>11 But that's one of the guiding foundations</p> <p>12 of your expert opinion, correct?</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: It's again</p> <p>15 established in the epidemiology</p> <p>16 literature, and I just applied</p> <p>17 that to the evidence that I</p> <p>18 assessed.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Okay. Actually my question</p> <p>21 is different, Doctor.</p> <p>22 That's one of the guiding</p> <p>23 principles of your expert report that --</p> <p>24 MS. MILLER: Object --</p>

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<p style="text-align: right;">Page 22</p> <p>1 BY MR. TISI:</p> <p>2 Q. -- you have weighed --</p> <p>3 MR. TISI: Wait.</p> <p>4 MS. MILLER: Sorry.</p> <p>5 BY MR. TISI:</p> <p>6 Q. -- that you have weighed</p> <p>7 cohort studies as a whole higher than</p> <p>8 case-control studies as a whole.</p> <p>9 MS. MILLER: Objection.</p> <p>10 She's asked -- she's answered this</p> <p>11 question like four times.</p> <p>12 THE WITNESS: And with all</p> <p>13 the interruptions, again, can --</p> <p>14 BY MR. TISI:</p> <p>15 Q. I'll rephrase the question.</p> <p>16 Okay. You asked what other</p> <p>17 epidemiologists do, and I'm asking you</p> <p>18 what you did.</p> <p>19 For the purposes of your</p> <p>20 report, did you -- the framework in which</p> <p>21 you looked at the different studies, you</p> <p>22 placed cohort studies higher than</p> <p>23 case-control studies?</p> <p>24 MS. MILLER: Same objection.</p>	<p style="text-align: right;">Page 24</p> <p>1 A. What I found is in the</p> <p>2 case-control studies, about 50 percent of</p> <p>3 the studies had a statistically</p> <p>4 significant result with regard to the</p> <p>5 association between talcum powder use and</p> <p>6 ovarian cancer. And I found within the</p> <p>7 cohort studies none of them had a</p> <p>8 statistically significant association</p> <p>9 between the use of perineal talcum powder</p> <p>10 and ovarian cancer.</p> <p>11 Q. And it was your opinion that</p> <p>12 the nonstatistically significant results</p> <p>13 were inconsistent with the statistically</p> <p>14 significant results?</p> <p>15 A. So if -- if some -- one</p> <p>16 thing is statistically significant and</p> <p>17 another thing is not statistically</p> <p>18 significant, those are two different</p> <p>19 things.</p> <p>20 Q. Okay. They may be two</p> <p>21 different things, but is it your opinion</p> <p>22 that they are contrary to each other?</p> <p>23 They are inconsistent?</p> <p>24 A. So when -- when I looked at</p>
<p style="text-align: right;">Page 23</p> <p>1 Just make sure you give me</p> <p>2 time to object.</p> <p>3 THE WITNESS: Thank you.</p> <p>4 So again, I looked at the</p> <p>5 evidence in totality and saw what</p> <p>6 it looked like. I applied</p> <p>7 established epidemiology</p> <p>8 principles that say cohort studies</p> <p>9 have higher degree of evidence for</p> <p>10 causality above case-control</p> <p>11 studies.</p> <p>12 BY MR. TISI:</p> <p>13 Q. And you relied, and we'll</p> <p>14 talk about this, the hierarchy, you</p> <p>15 referred to that as levels of evidence</p> <p>16 throughout your report, correct?</p> <p>17 A. I believe I do.</p> <p>18 Q. Okay. And you also found,</p> <p>19 and we'll talk about this, that the</p> <p>20 statistically significant results in the</p> <p>21 case-control studies were inconsistent</p> <p>22 and -- and contrary to the</p> <p>23 nonstatistically significant results of</p> <p>24 the non-case-control studies, correct?</p>	<p style="text-align: right;">Page 25</p> <p>1 the cohort studies, I believe --</p> <p>2 case-control studies, I want to make</p> <p>3 sure -- I believe that the range of -- of</p> <p>4 the risk ratios that -- that were shown</p> <p>5 went about -- were about fourfold and</p> <p>6 were higher than the cohort studies of</p> <p>7 which their range was maybe about</p> <p>8 1.75-fold, so much tighter and lower.</p> <p>9 Q. Okay. But my question is</p> <p>10 different. I'm focusing on statistical</p> <p>11 significance now.</p> <p>12 Is it your opinion that the</p> <p>13 nonstatistically significant results were</p> <p>14 contrary to the statistically significant</p> <p>15 results in the studies irrespective of</p> <p>16 study design?</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: So I'm not</p> <p>19 sure what you mean as contrary.</p> <p>20 And what statisticians, how</p> <p>21 statisticians and epidemiologists</p> <p>22 approach problems is you assume</p> <p>23 the null hypothesis is true, which</p> <p>24 would mean no association, and</p>

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<p>1 then you look to see if there's 2 evidence of an association. 3 So the cohort studies found 4 no evidence of an association and 5 about half of the -- in a 6 statistically significant sense, 7 and about half of the case-control 8 studies found a statistically 9 significant association. 10 BY MR. TISI: 11 Q. And so because of your -- 12 your opinion that statistically 13 significant results, insignificant 14 results prove the null, and -- and 15 statistically significant results suggest 16 an association, those two conflict with 17 each other and, therefore, we have 18 inconsistency? 19 MS. MILLER: Objection. 20 That mischaracterizes her 21 testimony. 22 THE WITNESS: So first of 23 all, you can't prove the null. 24 BY MR. TISI:</p>	<p>1 results are inconsistent with the 2 statistically insignificant results? 3 MS. MILLER: Objection. 4 We've now asked and answered this 5 I think ten times. 6 MR. TISI: Well, she hasn't 7 answered it. 8 BY MR. TISI: 9 Q. Go ahead. 10 MS. MILLER: I disagree. 11 BY MR. TISI: 12 Q. Are they -- are they 13 inconsistent in your opinion? 14 A. I believe, as I said, the 15 cohort studies find no association. 16 Q. Right. 17 A. And the case-control 18 studies, some of them find an 19 association, some do not. 20 Q. And so those are 21 inconsistent? 22 MS. MILLER: Objection. 23 THE WITNESS: Those are 24 clearly different.</p>
Page 27	Page 29
<p>1 Q. Okay. 2 A. Okay. And so, again, you 3 assume until -- it's sort of like law. 4 You assume innocence until proven guilty. 5 Q. Okay. 6 A. And so you assume no 7 association, and you have to see whether 8 or not there is evidence of an 9 association. 10 Q. Okay. So changing that a 11 little bit -- 12 MS. MILLER: Were you done? 13 Were you done answering? 14 THE WITNESS: Well, I'll -- 15 I was going to repeat again is 16 that in the cohort studies they 17 consistently found no association, 18 whereas in the case-control 19 studies, even among themselves, 20 some found an association and some 21 did not. 22 BY MR. TISI: 23 Q. Okay. And so your -- your 24 view was that statistically significant</p>	<p>1 BY MR. TISI: 2 Q. And so are they 3 inconsistent? 4 MS. MILLER: Objection. 5 THE WITNESS: Those -- those 6 again are clearly different. And 7 so if -- if -- I think it would be 8 a different situation if -- if, 9 you know, every single study found 10 an association which was not the 11 case here. 12 BY MR. TISI: 13 Q. Okay. But consistency is 14 one of the elements of the Bradford Hill 15 criteria, right? 16 A. That is correct. 17 Q. Okay. So I'm using a term 18 of art, okay. 19 Is it your opinion that -- 20 that the -- the statistically significant 21 results are inconsistent with the 22 statistically not significant results? 23 A. I think what I said and what 24 Bradford Hill said, that there -- there</p>

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<p>1 are two ways of looking at consistency. 2 The first level is whether 3 or not they are coming up with 4 statistical significance or not. So 5 the -- the case-control studies were 6 mixed with that. And the cohort studies 7 all came up with an -- a nonsignificant 8 result. 9 Q. Okay. So those are 10 inconsistent -- in your opinion. I 11 just -- I really want to focus on my -- 12 my question. 13 Is it your opinion that the 14 nonstatistically significant results that 15 you described of the cohort and some of 16 the case-control studies are inconsistent 17 with the case-controlled studies that 18 showed a statistically significant 19 result? 20 A. And again, I -- I don't know 21 how to answer other than to say that 22 there is a difference between something 23 that's statistically significant and 24 something that's not.</p>	<p>1 She's been dancing around the 2 question. 3 THE WITNESS: So the 4 case-control studies generally 5 report risk ratios greater than 6 one. A little over half are 7 statistically significant. And 8 the range of the magnitude of the 9 estimate is quite large. There's 10 no consistency between the -- 11 MS. SHARKO: You've got to 12 read much slower. 13 MR. TISI: We're going to 14 have one or two. We're going to 15 back to what you said -- what you 16 said to me yesterday, that we only 17 have one person. 18 MS. MILLER: All she said 19 was that she should read more 20 slowly. 21 MR. TISI: I understand. 22 MS. MILLER: I can tell her 23 that. 24 MR. LOCKE: If you would</p>
Page 31	Page 33
<p>1 If that's your definition of 2 inconsistency, then in that regard, they 3 are inconsistent. 4 Q. Doctor, I -- you applied the 5 Bradford Hill criteria which is 6 consistency is an element. And I'm 7 asking you, using that framework, are 8 statistically significant results that 9 you have described inconsistent with the 10 statistically significant results? 11 A. So give me a minute here. I 12 want to make -- I'm thinking perhaps I 13 stated it more clearly in here. 14 So it's my opinion that the 15 consistency of the association criteria 16 has not been demonstrated. 17 Q. And is that because there 18 are statistically significant results on 19 one hand and statistically insignificant 20 results on the other hand? 21 MS. MILLER: Objection. I 22 think she's now asked and answered 23 this 20 times. 24 MR. TISI: She hasn't.</p>	<p>1 encourage that, that was something 2 that you did in breach. 3 BY MR. TISI: 4 Q. Go ahead. 5 MS. MILLER: If you read too 6 quickly, the court reporter can't 7 take it down. 8 THE WITNESS: Sorry about 9 that. 10 So "Although the 11 case-control studies generally 12 report risk ratios greater than 13 one, and a little over half of the 14 studies had statistically 15 significant results, the range of 16 the magnitude is quite large." 17 And then I do say, "More 18 importantly there is no 19 consistency between the 20 case-control studies and the 21 cohort studies." 22 BY MR. TISI: 23 Q. And is that in part because 24 of the statistical significance?</p>

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<p>1 MS. MILLER: Objection. 2 THE WITNESS: I think I 3 just -- I just stated that there. 4 BY MR. TISI: 5 Q. Okay. Then that's -- then 6 that's the answer. I appreciate that. 7 Okay. Could you turn to 8 Page 53 of your -- first of all, after 9 weighing the evidence, did you reach a 10 conclusion about the causation question? 11 MS. MILLER: Objection. 12 Vague. 13 THE WITNESS: Yeah. What -- 14 MR. TISI: Okay. Let me ask 15 the question. 16 BY MR. TISI: 17 Q. After weighing all the 18 evidence that you collected, did you 19 reach a conclusion about whether, in your 20 opinion, to a reasonable degree of 21 certainty, that talcum powder does or 22 does not cause ovarian cancer? 23 A. So it is my professional 24 opinion that there is no evidence of a</p>	<p>1 principles in reaching that 2 conclusion. 3 BY MR. TISI: 4 Q. Okay. And in applying those 5 principles in your judgment, there is no 6 evidence of causation, true? 7 MS. MILLER: Objection. 8 That mischaracterizes the 9 testimony again. 10 MR. TISI: I'm asking the 11 question. I'm asking -- 12 MS. MILLER: Yeah, but 13 you're mischaracterized her 14 testimony. 15 MR. TISI: I'm asking her a 16 question, Counsel. You are -- 17 MS. MILLER: 18 Mischaracterizing her testimony. 19 MR. TISI: Fine, object. 20 MS. MILLER: I am. 21 MR. TISI: Good. 22 THE WITNESS: May you repeat 23 that, please. 24 BY MR. TISI:</p>
Page 35	Page 37
<p>1 causal relationship between talcum powder 2 exposure and ovarian cancer. 3 Q. And you used your 4 professional judgment based upon your 5 experience and training to reach that 6 conclusion? 7 A. It's based on my extensive 8 and rigorous review of the epidemiology 9 studies, and to some extent my review of 10 the scientific literature and my 11 experience and expertise in assessing 12 studies for level of evidence of the 13 data. 14 Q. Okay. And did you use your 15 professional judgment in reaching that 16 conclusion? 17 A. I don't know what you mean 18 by professional judgment. 19 Q. Did you -- did you use your 20 judgment in looking at the data? 21 A. I -- 22 MS. MILLER: Objection. 23 THE WITNESS: I'm sorry. 24 I applied epidemiological</p>	<p>1 Q. Yes, in your judgment based 2 upon your analysis of the evidence, the 3 epidemiologic and non-epidemiologic 4 evidence, you have concluded that there 5 is no risk of ovarian cancer with talcum 6 powder products? 7 MS. MILLER: Objection. 8 Same objection. 9 THE WITNESS: I'm sorry. I 10 keep not -- 11 I believe I said that I 12 applied established 13 epidemiological principles in 14 evaluating the data in totality 15 and came to the conclusion that 16 the evidence does not support a 17 causal relationship between talcum 18 powder exposure and ovarian 19 cancer. 20 BY MR. TISI: 21 Q. Now, if you look on Page 53, 22 of your report you have a conclusion. 23 A. Yes. 24 Q. And on the conclusion, you</p>

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<p>1 state the following. You state, "In my 2 professional opinion, there is no 3 evidence of a causal relationship between 4 perineal genital talcum powder exposure 5 and ovarian cancer. This is based on my 6 extensive and rigorous review of the 7 epidemiology studies, and to a lesser 8 extent my review of the scientific 9 literature, and my experience and 10 expertise in assessing studies for the 11 level of evidence in the data." 12 Did I read that correctly? 13 A. You did read that correctly. 14 Q. And that is your opinion? 15 A. It's what I wrote there. 16 Q. Okay. I'm going to mark, 17 just so we don't have to read the whole 18 report and come back to that. 19 (Document marked for 20 identification as Exhibit 21 Ballman-2.) 22 MR. TISI: This is your 23 opinion. I'm going to mark this 24 as Exhibit Number 2, which is the</p>	<p>1 A. I am not a gynecologist. 2 Q. You are not an oncologist? 3 A. I am not an oncologist. 4 Q. You are not now nor have you 5 ever been licensed to practice medicine 6 in any jurisdiction? 7 A. That is correct. 8 Q. You're not a toxicologist? 9 A. That is correct. 10 Q. You're not a mineralogist? 11 A. That is correct. 12 Q. You're not a geologist? 13 A. That is correct. 14 Q. In fact, you do not have a 15 formal degree from any university in 16 epidemiology, do you? 17 A. My degree is in operations 18 research. And it might be of interest 19 that Bradford Hill's degree actually was 20 in economics. And I feel we followed 21 sort of the same career path in that our 22 jobs that we took subsequently, first of 23 all, we had the basis, the quantitative 24 basis. I had some statistics courses as</p>
Page 39	Page 41
<p>1 statement that I just read. 2 BY MR. TISI: 3 Q. And you can keep that and 4 put that aside for a moment. We're going 5 to come back to that. 6 Are the bases for this 7 Ballman causation conclusion all 8 described in your epidemiology report 9 which we've marked as Exhibit Number 1? 10 A. I'm sorry. Could you repeat 11 the question? 12 Q. Yes. Are the bases for your 13 conclusion that is in Exhibit Number 2 14 all described in your report which is 15 Exhibit Number 1? 16 A. I believe that is the case. 17 I go through and support and describe the 18 methods that I used and the reasons why I 19 came to various conclusions. 20 Q. Okay. We discuss this in 21 more detail, but let me just back up for 22 a minute. 23 You're not a gynecologist, 24 true?</p>	<p>1 part of my degree. I also took some -- I 2 don't know if it was for credit or not -- 3 a seminar that was looking at sort of 4 confounding and biases in published 5 literature. And so that sort of sparked 6 my interest in statistics. And since 7 statistics was one of the tools in the 8 toolbox of operations research, my career 9 started going the direction of 10 statistics. 11 MR. TISI: Okay. I'm going 12 to move to strike. 13 BY MR. TISI: 14 Q. My question was: Do you 15 have a formal degree from any university 16 in epidemiology? 17 A. Again, I have no formal 18 degree, but I have extensive experience 19 in epidemiology and statistics through my 20 20 years of work. I mean, that's what I 21 do day in and day out. 22 Q. So the record is clear, you 23 do not have a Ph.D. in epidemiology, 24 correct?</p>

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<p>1 MS. MILLER: Objection. 2 THE WITNESS: My Ph.D. is in 3 operations research. But what I'm 4 saying is I have -- 5 BY MR. TISI: 6 Q. I understand what you're 7 saying. I need to -- 8 MS. MILLER: Please don't 9 interrupt the witness. 10 MR. TISI: No, we're going 11 to -- we're going to -- 12 MS. MILLER: No. No, you're 13 not going to interrupt her. 14 MR. TISI: We will call -- 15 no. We're going to call the 16 judge. I asked her a very 17 simple -- 18 MS. MILLER: That's fine. 19 MR. TISI: -- question. 20 MR. MILLER: That's fine if 21 you're going to call the judge -- 22 BY MR. TISI: 23 Q. Are you -- 24 MR. MILLER: -- and I'll</p>	<p>1 you do introduce yourself as a 2 statistician, correct? 3 MS. MILLER: Objection. 4 THE WITNESS: So it depends 5 what colleagues I'm introducing 6 myself to. I mean, sometimes I 7 introduce myself as a clinical 8 researcher. 9 BY MR. TISI: 10 Q. Okay. Do -- when you speak 11 to the FDA, do you introduce yourself as 12 a statistician? 13 A. When I speak to the FDA, I 14 do introduce myself as a statistician, 15 because usually, you know, it just again 16 depends upon what skills the individuals, 17 you know, are -- are in need at that 18 time. 19 But I have to say that there 20 is incredible overlap between 21 biostatistics and epidemiology. If you 22 look at any first textbook you will see 23 basically the same topics in -- whether 24 the book says epidemiology on it or</p>
Page 43	Page 45
<p>1 tell the judge that you are interrupting 2 the witness. 3 BY MR. TISI: 4 Q. Are you -- are you -- do you 5 hold a Ph.D. in -- in epidemiology? 6 MS. MILLER: Objection. 7 Asked and answered twice. 8 THE WITNESS: I do not have 9 a Ph.D. in epidemiology, but I was 10 explaining that I do have 11 extensive experience in statistics 12 and epidemiology. That's all I've 13 been doing, living and breathing 14 for the last 20 years. 15 BY MR. TISI: 16 Q. Do you have a masters degree 17 in epidemiology? 18 A. My masters degree is in 19 operations research which contains, 20 again, some statistical training and some 21 training in epidemiology. But the formal 22 degree is operations research. 23 Q. In fact, when you introduce 24 yourself to your professional colleagues,</p>	<p>1 whether the book says statistics on it. 2 And, in fact, many departments and 3 divisions across the country, like my 4 own, are departments and divisions of 5 biostatistics and epidemiology, just due 6 to the amount of overlap when it comes to 7 medical research. 8 Q. Doctor, I'm going to -- I'm 9 really going to stop and we're going to 10 call the judge. 11 I am asking you a very 12 simple, straightforward question. 13 When you introduce yourself 14 to the FDA, do you list yourself as a 15 statistician, yes or no? 16 MS. MILLER: Objection. 17 Objection. If she doesn't feel 18 like yes or no is a proper answer, 19 she needs to give you the full 20 context. 21 MR. TISI: Well, she -- I 22 will ask her -- if she needs to 23 give me full context, she can tell 24 me that and I will then ask a</p>

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<p style="text-align: right;">Page 46</p> <p>1 follow-up. 2 MS. MILLER: Please don't -- 3 BY MR. TISI: 4 Q. Are you -- when you 5 introduce yourself to the FDA -- 6 MS. MILLER: Please don't 7 argue with me. 8 BY MR. TISI: 9 Q. -- do you introduce yourself 10 as a statistician? 11 A. When we go around the room 12 and say -- I -- I say I -- when I 13 introduce myself around the room, when we 14 have to introduce ourselves at FDA 15 meetings, I say, usually, "I'm Karla 16 Ballman, the division chief of 17 biostatistics and epidemiology. I am a 18 statistician." 19 Q. Okay. When you apply for 20 grants for research, do you describe 21 yourself as a statistician? 22 A. I don't know if I state 23 anywhere in a grant for research as to if 24 I'm a statistician or not. It's usually</p>	<p style="text-align: right;">Page 48</p> <p>1 researched the causation question that 2 you are here to testify about today? 3 A. I had read some literature. 4 Q. Okay. 5 A. Did not perform formal 6 research. 7 Q. Okay. Had you ever reached 8 a conclusion about whether or not talcum 9 powder products cause ovarian cancer 10 before being retained by Ms. Sharko? 11 A. No. 12 Q. Prior to being retained by 13 Johnson & Johnson lawyers to defend them 14 in lawsuits, have you ever expressed an 15 opinion one way or the other as to 16 whether or not talcum powder products are 17 capable of causing ovarian cancer? 18 MS. MILLER: Objection. She 19 wasn't retained to defend us. 20 MR. TISI: Okay. Then let 21 me rephrase the question. 22 MS. MILLER: But we're the 23 lawyers. Not -- not she. 24 BY MR. TISI:</p>
<p style="text-align: right;">Page 47</p> <p>1 investigator or co-investigator. 2 Q. Okay. Let's move to another 3 topic. 4 You know I represent women 5 who claim their use of Johnson & 6 Johnson's talcum powder products caused 7 ovarian cancer, true? 8 A. I -- I don't know what you 9 do. 10 Q. Okay. When we were first -- 11 when were you first contacted by J&J's 12 lawyers to consult on the question that 13 you have given your report on regarding 14 the link between ovarian cancer and 15 talcum powder products, or the lack of a 16 link? 17 MS. MILLER: Objection. 18 THE WITNESS: I was 19 contacted by Johnson & Johnson 20 lawyers, I was contacted by 21 Ms. Sharko in November of 2018. 22 BY MR. TISI: 23 Q. Okay. Prior to being 24 retained by lawyers at J&J, have you ever</p>	<p style="text-align: right;">Page 49</p> <p>1 Q. Where -- before being 2 contacted by the lawyers to be a 3 potential expert in litigation involving 4 women who claim that they may die as a 5 result of ovarian cancer caused by talcum 6 powder products, did you ever express an 7 opinion about whether or not talcum 8 powder products cause ovarian cancer? 9 MS. MILLER: Objection. 10 Your restated question was as 11 objectionable as your first 12 question. 13 THE WITNESS: And I'm sorry. 14 That was a very long question. So 15 I don't know when I answer it 16 what -- what I'm agreeing to and 17 what I'm not agreeing to, so could 18 you -- 19 BY MR. TISI: 20 Q. Prior to -- then let me 21 rephrase the question. 22 Prior to November of 2018 23 have you ever expressed an opinion as to 24 whether or not talcum powder products</p>

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<p style="text-align: right;">Page 50</p> <p>1 cause ovarian cancer?</p> <p>2 A. Not in any sort of formal</p> <p>3 sense. I don't know if in casual</p> <p>4 conversation someone may have said what</p> <p>5 do you think. But no, I didn't read a</p> <p>6 form -- a formal opinion.</p> <p>7 Q. Okay. Is it fair to say</p> <p>8 that the opinions that you have on the</p> <p>9 subject about whether or not talcum</p> <p>10 powder products cause ovarian cancer</p> <p>11 occurred after you've spoke to the</p> <p>12 lawyers for the first time in November of</p> <p>13 2018?</p> <p>14 MS. MILLER: Objection.</p> <p>15 THE WITNESS: So my opinion</p> <p>16 as to whether or not there is</p> <p>17 evidence that talcum powder causes</p> <p>18 ovarian cancer, is based upon the</p> <p>19 research that I had done.</p> <p>20 I -- I did not reach a</p> <p>21 formal opinion until I had done</p> <p>22 the research and looked at the</p> <p>23 data in totality.</p> <p>24 BY MR. TISI:</p>	<p style="text-align: right;">Page 52</p> <p>1 BY MR. TISI:</p> <p>2 Q. And that would have been</p> <p>3 after you met with the lawyers for</p> <p>4 Johnson & Johnson, correct?</p> <p>5 A. I was --</p> <p>6 MS. MILLER: Objection.</p> <p>7 Please remember to give me</p> <p>8 time to object.</p> <p>9 THE WITNESS: I did not</p> <p>10 start the research until after</p> <p>11 November 2018.</p> <p>12 BY MR. TISI:</p> <p>13 Q. When you first met the</p> <p>14 Johnson & Johnson lawyers?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: Again, I had</p> <p>17 no reason to do any research</p> <p>18 before that, and so I started the</p> <p>19 research after I was retained to</p> <p>20 do -- to render an opinion.</p> <p>21 BY MR. TISI:</p> <p>22 Q. Now, is it fair to say that</p> <p>23 you never published on the subject of</p> <p>24 talcum powder and ovarian cancer?</p>
<p style="text-align: right;">Page 51</p> <p>1 Q. And that was after November</p> <p>2 of 2018?</p> <p>3 A. Well, I -- I -- that's when</p> <p>4 I started the research --</p> <p>5 Q. Right.</p> <p>6 A. -- on -- on the issue.</p> <p>7 Q. So the answer to my question</p> <p>8 is, the first time you ever reached a</p> <p>9 conclusion based upon your evaluation of</p> <p>10 the data did not occur until after you</p> <p>11 first met with Ms. Sharko in 2018 --</p> <p>12 MS. MILLER: Object.</p> <p>13 BY MR. TISI:</p> <p>14 Q. -- November?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: So -- so how I</p> <p>17 would say it is I did not start</p> <p>18 doing research on the issue until</p> <p>19 after November of 2018. And as a</p> <p>20 result of that research, I reached</p> <p>21 a conclusion which obviously,</p> <p>22 since I didn't start the research</p> <p>23 until November, I didn't reach the</p> <p>24 conclusion until after November.</p>	<p style="text-align: right;">Page 53</p> <p>1 A. That is correct. There are</p> <p>2 no publications with my name on it.</p> <p>3 Q. And though you have by my</p> <p>4 count over 200 publications in the</p> <p>5 literature, you didn't cite any of your</p> <p>6 own literature for -- or any of your</p> <p>7 published work in your report, correct?</p> <p>8 A. I again just used the</p> <p>9 research tools that I use when I do any</p> <p>10 sort of research. And, you know, there</p> <p>11 are many publications, as you see, that I</p> <p>12 have there where I cite none of my own</p> <p>13 work. I just use what's relevant to</p> <p>14 doing the research for the question at</p> <p>15 hand.</p> <p>16 Q. And your work was not</p> <p>17 relevant to your report, correct?</p> <p>18 MS. MILLER: Objection.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Or you would have cited it?</p> <p>21 MS. MILLER: Objection.</p> <p>22 THE WITNESS: So my</p> <p>23 experience is extremely relevant</p> <p>24 to my opinion, and my work is my</p>

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<p style="text-align: right;">Page 54</p> <p>1 experience. And so --</p> <p>2 BY MR. TISI:</p> <p>3 Q. Okay. But your published</p> <p>4 research, you did not rely on any of your</p> <p>5 published research in crafting your</p> <p>6 report because it's not -- it's not in</p> <p>7 the bibliography or the -- anything</p> <p>8 relied on that was given to us, so I'll</p> <p>9 represent to you that I looked through</p> <p>10 all -- all of your citations, and there's</p> <p>11 not a single reference to any of your</p> <p>12 published work. Is that accurate?</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: So there are</p> <p>15 no references --</p> <p>16 BY MR. TISI:</p> <p>17 Q. Okay.</p> <p>18 A. -- to my own published work.</p> <p>19 But that wasn't necessary -- in my --</p> <p>20 that -- because it was based upon my</p> <p>21 experience and I used what were the</p> <p>22 relevant pieces of the epidemiology and</p> <p>23 actually, you know, the reports that I</p> <p>24 read, and that is in my report.</p>	<p style="text-align: right;">Page 56</p> <p>1 A. Yes. I do reference this</p> <p>2 article.</p> <p>3 Q. Okay. Since 1982, you would</p> <p>4 agree with me that there are over 30</p> <p>5 epidemiologic studies that have been</p> <p>6 published?</p> <p>7 A. Since this time, I believe</p> <p>8 the studies that I have in my report and</p> <p>9 I reviewed included a total of about 30</p> <p>10 that were case-control studies or cohort</p> <p>11 studies, and meta-analyses.</p> <p>12 Q. Right. So between 1982 and</p> <p>13 the time that we sit here today in 2019,</p> <p>14 there are over 30 studies, and these</p> <p>15 include population-based case-control</p> <p>16 studies, correct?</p> <p>17 A. There are population-based</p> <p>18 case-control studies.</p> <p>19 Q. They include hospital-based</p> <p>20 case-control studies, right?</p> <p>21 A. There are hospital-based</p> <p>22 case-control studies.</p> <p>23 Q. Cohort studies, which you</p> <p>24 mentioned.</p>
<p style="text-align: right;">Page 55</p> <p>1 Q. Okay. And you know that the</p> <p>2 first epidemiologic study that described</p> <p>3 the potential association between talcum</p> <p>4 powder products and ovarian cancer was</p> <p>5 published by researchers out of Harvard</p> <p>6 University in 1982, correct?</p> <p>7 MS. MILLER: Objection.</p> <p>8 THE WITNESS: So it -- I</p> <p>9 don't know with complete</p> <p>10 confidence, but I do know that the</p> <p>11 first publication that I reviewed</p> <p>12 that had an association in it, I</p> <p>13 believe was in 1982 by Cramer.</p> <p>14 BY MR. TISI:</p> <p>15 Q. Okay. I'm just going to,</p> <p>16 for purposes of the record, I will attach</p> <p>17 the Cramer article as Exhibit Number 3.</p> <p>18 (Document marked for</p> <p>19 identification as Exhibit</p> <p>20 Ballman-3.)</p> <p>21 BY MR. TISI:</p> <p>22 Q. Is that the same -- Exhibit</p> <p>23 Number 3 the Cramer article that you</p> <p>24 referenced?</p>	<p style="text-align: right;">Page 57</p> <p>1 A. There are cohort studies.</p> <p>2 Q. Meta-analyses of the</p> <p>3 epidemiologic studies?</p> <p>4 A. There are meta-analyses of</p> <p>5 the observational studies.</p> <p>6 Q. A pooled analysis?</p> <p>7 A. There is a pooled analysis.</p> <p>8 Q. And there are biologic</p> <p>9 studies, which you also refer to?</p> <p>10 A. There are -- there are some</p> <p>11 biological studies.</p> <p>12 Q. Okay. And of all those</p> <p>13 studies in the past 40 years, you have</p> <p>14 not been involved in any of them, your</p> <p>15 name doesn't appear in any of those</p> <p>16 studies, correct?</p> <p>17 A. I am not an author on any of</p> <p>18 those studies that you cited.</p> <p>19 Q. Well, you were not involved</p> <p>20 in any way in any of those studies,</p> <p>21 correct, because your involvement in</p> <p>22 this -- this issue didn't really happen</p> <p>23 until after November of 2018, correct?</p> <p>24 A. So involvement, I'm not sure</p>

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<p style="text-align: right;">Page 58</p> <p>1 how to quite interpret that. I mean, I 2 have vast amount of experience of 3 analyzing data that are in these types of 4 studies -- 5 MS. MILLER: Please don't 6 interrupt her. 7 THE WITNESS: -- in terms of 8 coming to a conclusion. 9 BY MR. TISI: 10 Q. Doctor, I'm not asking you 11 what your background is now. I'm asking 12 you prior to November of 2018, had you 13 ever been involved in any study, 14 observational or otherwise, in any 15 capacity involving talcum and ovarian 16 cancer? 17 A. I have no publications in 18 talc and ovarian cancer. 19 Q. I'm not limiting it to 20 publications. I'm asking you, had you 21 had any involvement in any fashion with 22 any study involving ovarian cancer and 23 talc? 24 A. So again, I'm not sure what</p>	<p style="text-align: right;">Page 60</p> <p>1 for over 40 years. You've seen -- you've 2 seen articles across the spectrum, 3 correct? 4 MR. LOCKE: Objection. 5 MS. MILLER: Objection. 6 That's like seven different 7 questions all in one. 8 MR. TISI: Yes. 9 BY MR. TISI: 10 Q. There are multiple 11 scientists -- let me rephrase the 12 question. 13 There are multiple 14 scientists from multiple disciplines that 15 have looked at the questions related to 16 ovarian cancer and talc for over 17 40 years, true? 18 MS. MILLER: Objection. 19 THE WITNESS: So I don't 20 know what you mean by "multiple." 21 But when there's any sort of topic 22 that's researched, it involves, 23 you know, many different people. 24 It's never -- I mean, it's not</p>
<p style="text-align: right;">Page 59</p> <p>1 you mean by the term "involvement." I 2 mean -- 3 Q. Did anyone -- then I'll 4 rephrase it. Okay. 5 Did anyone ever call you and 6 say, "You know, we're doing a study, 7 Dr. Ballman. Can you give us your 8 informal advice on how to design it," 9 involving ovarian cancer -- 10 MS. MILLER: Objection. 11 BY MR. TISI: 12 Q. -- and talcum powder 13 products? 14 MS. MILLER: Objection. 15 THE WITNESS: I have not 16 received such a phone call. 17 BY MR. TISI: 18 Q. Okay. And would you agree 19 with me that there are literally dozens 20 of scientists that have been involved in 21 this issue over 40 years, involved in the 22 epidemiology studies, toxicologists, 23 pharmacologists, mineralogist, have been 24 involved in the ovarian cancer talc issue</p>	<p style="text-align: right;">Page 61</p> <p>1 valuable research if it's just one 2 person. So I don't think talcum 3 powder and ovarian cancer is any 4 different from any other research 5 field that you had mentioned. 6 BY MR. TISI: 7 Q. Right. And so the answer to 8 the question is there are literally 9 dozens of scientists across the spectrum 10 that have been looking at these issues 11 and publishing in this area for 40 years, 12 true? 13 MS. MILLER: Objection. 14 THE WITNESS: I can't answer 15 that with certainty. I don't know 16 how many scientists. I don't know 17 how long it's been -- 18 BY MR. TISI: 19 Q. There are many. How about 20 many? 21 A. Just like any other research 22 topic, it's -- it's what one would 23 expect, yes. 24 Q. Okay. Have any of them been</p>

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Page 62	Page 64
<p>1 you?</p> <p>2 MS. MILLER: Objection.</p> <p>3 We've been through this.</p> <p>4 THE WITNESS: You know, I --</p> <p>5 I have not done myself a study in</p> <p>6 ovarian cancer, a published study</p> <p>7 in ovarian cancer and talc. I</p> <p>8 have done research on this topic</p> <p>9 as we talked about after</p> <p>10 November 2018 --</p> <p>11 BY MR. TISI:</p> <p>12 Q. Okay.</p> <p>13 A. -- using all the expertise I</p> <p>14 have in similar types of studies that</p> <p>15 I've been involved in, but just didn't</p> <p>16 have the topic ovarian cancer and talcum</p> <p>17 powder.</p> <p>18 Q. Now, I can represent to you</p> <p>19 that Johnson & Johnson has produced, as</p> <p>20 they tell me all the time, millions of</p> <p>21 pages of documents in connection with</p> <p>22 this litigation. And I'll represent that</p> <p>23 to you. And that covers the time span</p> <p>24 since the 1960s and perhaps even before.</p>	<p>1 MS. MILLER: Objection.</p> <p>2 Asked and answered.</p> <p>3 THE WITNESS: Yeah, again, I</p> <p>4 just don't know why -- why a</p> <p>5 company -- I -- I don't know how</p> <p>6 companies operate. I don't know</p> <p>7 if they engage experts to do</p> <p>8 research for them necessarily.</p> <p>9 I mean, some companies may</p> <p>10 and some companies may not, I just</p> <p>11 don't know.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Johnson & Johnson never</p> <p>14 contacted you in 40 years to ever perform</p> <p>15 a study or advise them in any fashion</p> <p>16 about either how to design a study to</p> <p>17 look at the question of ovarian cancer,</p> <p>18 did they?</p> <p>19 A. I --</p> <p>20 MS. MILLER: Objection.</p> <p>21 Please give me ten seconds.</p> <p>22 THE WITNESS: I know it.</p> <p>23 I'm so sorry.</p> <p>24 MS. MILLER: That's all it</p>
Page 63	Page 65
<p>1 Would it surprise you that</p> <p>2 your name, Karla Ballman, isn't mentioned</p> <p>3 as having been contacted even once by</p> <p>4 Johnson & Johnson on the issue of ovarian</p> <p>5 cancer and talcum powder products in that</p> <p>6 whole time?</p> <p>7 MS. MILLER: Objection.</p> <p>8 THE WITNESS: I wouldn't --</p> <p>9 I'm -- don't even know how to</p> <p>10 answer that.</p> <p>11 I -- I wouldn't know why a</p> <p>12 company would contact me or have</p> <p>13 my name in any sort of documents</p> <p>14 that -- that they generated if I</p> <p>15 hadn't been working with the</p> <p>16 company. I just don't know how to</p> <p>17 answer that.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Would it surprise you that</p> <p>20 there's no -- nobody ever mentioned we</p> <p>21 need to contact Karla Ballman and obtain</p> <p>22 her expertise about whether or not talcum</p> <p>23 powder product caused ovarian cancer in</p> <p>24 that 40-year period?</p>	<p>1 takes.</p> <p>2 THE WITNESS: Again, I'm</p> <p>3 just at a loss. I don't know why</p> <p>4 they would.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Okay. Well --</p> <p>7 A. Because again, I don't know</p> <p>8 if they do research. I don't know if</p> <p>9 they contact people to do research from</p> <p>10 them for them, so I -- I just don't --</p> <p>11 Q. Well, I'll represent to you</p> <p>12 that they have. Okay.</p> <p>13 Among other people they've</p> <p>14 contacted, do you know who Ken Rothman</p> <p>15 is?</p> <p>16 A. No.</p> <p>17 Q. You don't know -- you</p> <p>18 testified in your Viagra litigation that</p> <p>19 you knew who Ken Rothman was. He's an</p> <p>20 epidemiologist who published a textbook</p> <p>21 on epidemiology.</p> <p>22 A. Oh, yeah.</p> <p>23 Q. Do you remember that?</p> <p>24 A. Yeah, yeah, yeah, yeah,</p>

17 (Pages 62 to 65)

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<p style="text-align: right;">Page 66</p> <p>1 yeah. I don't know him personally. 2 Q. Right. But he is a -- he is 3 a well-established epidemiologist, 4 correct? 5 MS. MILLER: Objection. 6 THE WITNESS: He is an 7 epidemiologist and I've heard his 8 name. 9 BY MR. TISI: 10 Q. Right. And you also -- 11 and -- contacted Drs. Huncharek and 12 Muscat. You've seen those names, 13 correct? 14 A. I have seen those names. 15 Q. Okay. And I'm going to tell 16 you, over the course of 40 years, they 17 have contacted people from various 18 disciplines to -- for various questions 19 related to talc and ovarian cancer. I 20 want to ask you to assume that that is 21 true. And I will -- 22 MS. MILLER: Objection. 23 MR. TISI: I haven't even 24 asked the question, counsel.</p>	<p style="text-align: right;">Page 68</p> <p>1 it's unusual. I'm just asking you the 2 simple question. They never -- none of 3 the lawyers -- excuse me. 4 None of the scientists at 5 Johnson & Johnson ever contacted you over 6 the past 40 years to seek your advice, 7 true? 8 A. I have not been -- 9 MS. MILLER: Objection. 10 THE WITNESS: Oh, sorry. 11 BY MR. TISI: 12 Q. You may answer. 13 A. Yeah. 14 Q. She is going to object to 15 everything, so just -- 16 A. I'll wait, I need to wait. 17 MS. MILLER: I'm not going 18 to object if you don't ask 19 objectionable questions. 20 MR. TISI: Okay. 21 MS. MILLER: It's a simple 22 solution. 23 THE WITNESS: I have not 24 been contacted by anyone in</p>
<p style="text-align: right;">Page 67</p> <p>1 MS. MILLER: I didn't even 2 know. I can't tell what's a 3 question and what's a lecture. 4 MR. TISI: Well, then 5 wait -- wait till the end. 6 BY MR. TISI: 7 Q. At no time did any scientist 8 or regulatory person from Johnson & 9 Johnson ever contact Dr. Ballman to ask 10 her opinions until the lawyers contacted 11 you in November of 2018, would that be a 12 true statement? 13 MS. MILLER: Objection. 14 THE WITNESS: Again, as I 15 said, I -- I just don't know how 16 companies operate. You tell me 17 they've had -- they hire experts 18 and I have no evidence one way or 19 another if they do. 20 But I had not been contacted 21 by Johnson & Johnson, but I don't 22 know if that's unusual. I just -- 23 BY MR. TISI: 24 Q. I'm not asking you whether</p>	<p style="text-align: right;">Page 69</p> <p>1 Johnson & Johnson. 2 BY MR. TISI: 3 Q. Related to the issue of 4 talcum powder products and ovarian 5 cancer, true? 6 A. If you don't count the 7 lawyers, and I'm not sure what that 8 relationship means, I -- I have not. 9 Q. Okay. Would it surprise you 10 that when we looked in the Johnson -- in 11 the millions of pages of documents that 12 Johnson & Johnson sent to us, that not a 13 single article of research that you have 14 ever done has appeared in -- in any 15 bibliography for any issue related to 16 ovarian cancer, would that surprise you? 17 MS. MILLER: Objection. 18 THE WITNESS: You know, 19 again, I don't know what documents 20 or what's in those million pages. 21 So I don't know if that would 22 surprise me or not. 23 BY MR. TISI: 24 Q. Well, can you think of any</p>

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<p>1 article that you've ever written that 2 would be relevant to the question of 3 whether or not ovarian cancer is caused 4 by talcum powder products? 5 MS. MILLER: Objection. 6 THE WITNESS: Well, I have 7 expertise in other -- in -- in 8 just sort of this type of thing in 9 general. But if -- if it's 10 related to ovarian cancer and 11 talcum powder as we discussed, 12 there would not be any 13 publications with my name on it 14 that -- that address ovarian 15 cancer and talcum powder. 16 BY MR. TISI: 17 Q. Now, even as of today, we're 18 now in March of 2019, since Ms. Sharko 19 found you as an expert witness in this 20 litigation, have you ever been in contact 21 with any J&J scientist that -- where they 22 said well, now that we found you, 23 Dr. Ballman, maybe you can help us design 24 a study or give us your advice on</p>	<p>1 Q. Okay. And that would be for 2 research, correct? 3 A. I haven't been contacted by 4 anyone in Johnson & Johnson. 5 Q. And that would be to help 6 them in any regulatory issue, correct? 7 A. I have not been contacted by 8 anyone in Johnson & Johnson. 9 Q. Okay. So it's the 10 company -- and I'm distinction the 11 company from the lawyers. 12 The company has not spent 13 any time and effort trying to understand 14 your opinions or the basis of it, just 15 the lawyers, true? 16 MS. MILLER: Objection. 17 THE WITNESS: Again, I'm not 18 sure how to answer that because I 19 was retained in terms of the 20 litigation. I don't know if 21 there's any rules that surround 22 that or whatever. I have no idea. 23 BY MR. TISI: 24 Q. But the answer would be no,</p>
Page 71	Page 73
<p>1 causation or any -- anything related to 2 talcum powder products and ovarian 3 cancer, have you spoken to any scientist 4 at J&J since November of 2018? 5 A. I have not spoke -- 6 MS. MILLER: You've got to 7 let me object. There was like, 8 seven questions in there. You've 9 got to give me time to object. 10 That was objectionable. 11 THE WITNESS: Can you 12 rephrase? Not rephrase. Just 13 repeat. 14 BY MR. TISI: 15 Q. Since you've been found as 16 an expert witness in November of 2018, 17 has any scientist at Johnson & Johnson 18 reached out to you to ask your opinion on 19 talcum powder products and ovarian 20 cancer? 21 A. Since I have been retained 22 by the lawyer -- by Johnson & Johnson in 23 2018 for this case, I have not been 24 contacted by anyone in Johnson & Johnson.</p>	<p>1 you've not been retained and spoken to 2 anybody at Johnson & Johnson in 3 connection with any scientific question 4 outside of the legal arena, correct? 5 A. As I mentioned, I have not, 6 as far as I know, talked to anyone from 7 Johnson & Johnson. 8 Q. In fact, Johnson & Johnson 9 makes hundreds of products for 10 pharmaceuticals, medical devices and 11 cosmetics. You know that to be true, 12 correct? 13 MS. MILLER: Objection. 14 THE WITNESS: I know they 15 make lots of products. I don't 16 know how many. I don't know what 17 the span is of the different 18 areas. 19 BY MR. TISI: 20 Q. Has any Johnson & Johnson 21 scientist ever reached out to you to help 22 them understand any scientific question 23 for any reason? 24 MS. MILLER: Objection.</p>

19 (Pages 70 to 73)

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<p>1 THE WITNESS: Again, I don't 2 know how companies operate. I 3 don't know -- I mean I presume 4 they have their own scientists. 5 I'm not sure if they are reaching 6 out. I just -- 7 BY MR. TISI: 8 Q. I'm asking you what they did 9 for you. And I am not asking you to get 10 in their mind and figure out what their 11 policies are or anything like that. 12 Has Johnson & Johnson, any 13 Johnson & Johnson scientist ever reached 14 out to Dr. Karla Ballman to ask her help 15 in understanding any scientific question 16 for any reason? 17 A. Again, I have not talked to 18 anyone in an official capacity from 19 Johnson & Johnson. 20 Q. And you have a career 21 spanning how many decades now? 22 A. Oh, easily about two to 23 three decades. 24 Q. Okay. And in that two or</p>	<p>1 A. I believe -- myself, or just 2 the institution I work for? 3 Q. Your team. You and your -- 4 anybody that you may collaborate with? 5 A. There might have been one or 6 two occasions. 7 Q. Okay. But they've not been 8 Johnson & Johnson? 9 A. That is correct. 10 Q. Johnson & Johnson never 11 asked you to represent them on any issue 12 before the FDA related to talcum powder 13 products, have they? 14 MS. MILLER: Objection. 15 THE WITNESS: I have not 16 been before the FDA on behalf of 17 Johnson & Johnson. 18 BY MR. TISI: 19 Q. For any reason including -- 20 A. For any reason. 21 Q. Okay. You know that IARC 22 looked at the question of ovarian cancer 23 and talcum powder products in 2006 24 correct?</p>
Page 75	Page 77
<p>1 three decades, no one from Johnson & 2 Johnson ever reached out to you and asked 3 you, "Hey, you know, we got this problem 4 here. Can you help us design a study or 5 analyze data, perform a causation 6 analysis," anything scientist related? 7 MS. MILLER: Objection. 8 THE WITNESS: So I am in 9 academia. So, you know, I don't 10 know why they would necessarily 11 reach out to me in particular. No 12 other companies do either. 13 BY MR. TISI: 14 Q. You've never done studies 15 for any company? 16 A. I didn't say that. 17 Q. Okay. You've done studies 18 for companies, true? You've done studies 19 that have been sponsored by companies, 20 correct? 21 A. So now you'll have to 22 define -- 23 Q. Have you received funding 24 from companies to do studies?</p>	<p>1 A. I read a report from IRAC 2 (sic) who -- that looked at that 3 question. 4 Q. And were you asked by 5 anybody in the talc industry to help them 6 understand that talc-ovarian-cancer 7 connection in connection with the IARC 8 proceedings in 2006? 9 A. I was not part of the IRAC 10 (sic) committee that looked at that 11 question. 12 Q. You say IRAC. Is it IRAC 13 or -- 14 A. I'm sorry. IARC. I know. 15 I did that -- I do that often. 16 Q. That's okay. I do it too. 17 A. It's IARC. 18 Q. Okay. And what does IARC 19 stand for? 20 A. International Agency -- I 21 don't remember the title. I can get it. 22 Q. Did J&J scientists -- 23 MS. MILLER: Wait. She's 24 looking for the answer.</p>

20 (Pages 74 to 77)

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<p style="text-align: right;">Page 78</p> <p>1 MR. TISI: Actually, that's 2 fine. 3 MS. MILLER: Are you 4 striking the question? 5 MR. TISI: No, I just -- 6 it's fine. 7 MS. MILLER: If you're not 8 striking the question -- 9 MR. TISI: She didn't 10 know -- she didn't know the 11 answer. 12 MS. MILLER: Well, she's 13 checking her report and she'd like 14 to finish answering. 15 BY MR. TISI: 16 Q. Do you know without looking 17 in your report, Doctor? 18 A. I am not very good at all 19 acronyms and stuff. 20 Q. Okay. 21 A. And as you see I don't even 22 pronounce them correctly because I get 23 the letters mixed up. So I want to be 24 correct when I say what the title is</p>	<p style="text-align: right;">Page 80</p> <p>1 they someone that you come in contact 2 with through the literature and your 3 understanding of the -- of cancer and 4 cancer research? 5 MS. MILLER: Objection. 6 That was two questions. 7 THE WITNESS: Again, as I 8 said, I mean, IARC is an 9 established committee that people 10 know do research on cancer to 11 determine whether or not there is 12 carcinogenic risk to humans and 13 people refer to them, as I do 14 myself. 15 BY MR. TISI: 16 Q. And are they -- when you say 17 refer to them, they rely on them, 18 correct? 19 MS. MILLER: Objection. 20 THE WITNESS: I'm not sure 21 what you mean rely on them. 22 BY MR. TISI: 23 Q. You go -- 24 A. I mean, they go -- I go -- I</p>
<p style="text-align: right;">Page 79</p> <p>1 of -- of that agency. 2 And it's right here 3 somewhere. International Agency For 4 Research on Cancer. 5 Q. Have you ever been asked by 6 can IARC to participate in any 7 deliberation about whether or not a 8 substance causes cancer? 9 A. I have not been on any IARC 10 committee. 11 Q. Has IARC a well respected 12 scientific organization? 13 MS. MILLER: Objection. 14 THE WITNESS: I believe IARC 15 gets experts in the areas that 16 they need to adjust -- to address 17 the questions that come before 18 them or that they deem of 19 interest. 20 BY MR. TISI: 21 Q. Do you -- 22 A. That's all I know. 23 Q. Do you consider them a well 24 respected scientific organization? Are</p>	<p style="text-align: right;">Page 81</p> <p>1 look at them to see what -- what their 2 evidence is and what their conclusions 3 are. 4 Q. Okay. Are they considered 5 to be a respectable scientific 6 organization? 7 MS. MILLER: Objection. 8 THE WITNESS: They -- again, 9 they are an organization. I mean, 10 it depends upon what you mean by 11 respectable. I mean, as I said 12 they're well established. I use 13 them as a reference. Many other 14 people use them as references. 15 BY MR. TISI: 16 Q. Okay. Now, this IARC report 17 that you refer to in your report was 18 issued in 2010. But you do understand 19 that IARC looked at evidence before 2006, 20 correct? It was published in 2010, but 21 the conclusions were reached as of 2006. 22 Do you understand that to be true? 23 MS. MILLER: Objection. 24 THE WITNESS: I -- I believe</p>

21 (Pages 78 to 81)

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<p>1 I'd have to look at the dates to 2 make sure. But I -- I do agree 3 that the actual monograph came out 4 after they had done analyses and 5 the data that they use for that 6 analyses. 7 BY MR. TISI: 8 Q. Now, you do know that in 9 December 2018, two months before you 10 issued your litigation report for J&J's 11 lawyers, Health Canada looked at the 12 question as to whether or not, in your 13 words, the epidemiology studies and 14 scientific literature supported a causal 15 relationship between talcum powder 16 products and ovarian cancer. 17 Do you -- do you know that 18 to be true? 19 MS. MILLER: Objection. 20 THE WITNESS: So are you 21 asking me if I'm aware that Health 22 Canada has issued a -- could -- 23 could you rephrase that? 24 BY MR. TISI:</p>	<p>1 time that you wrote your report? 2 A. I -- I actually looked it up 3 before -- as I was writing my report, 4 before it was finalized. 5 Q. Okay. So you were familiar 6 with it, but didn't list it in your 7 report as something that you had 8 considered in connection with your 9 opinions? 10 A. I did not reference it. 11 And -- and actually, I may have 12 misspoken. I -- it's been such a blur 13 these last two year -- months -- I 14 don't -- even years, it feels like years. 15 I -- I'm not sure exactly 16 when I looked at what, so -- but I do 17 believe I did see it before I finalized 18 my report, because I do reference the 19 Taher meta-analysis. 20 Q. Right. Well, you know the 21 Taher meta-analysis was commissioned by 22 Health Canada and then used in the Health 23 Canada report, you know that they are two 24 separate reports?</p>
Page 83	Page 85
<p>1 Q. Yes. Yes. Do you know that 2 in December 2018 they issued a, call it a 3 draft report, about assessing the various 4 lines of evidence using the Bradford Hill 5 criteria on the question about whether or 6 not talcum powder products is capable of 7 causing ovarian cancer? 8 A. I know that Health Canada 9 has issued -- did issue a draft report 10 late last year. 11 Q. Okay. And you know that 12 they looked at the evidence through the 13 Bradford Hill criteria, correct? 14 MS. MILLER: Objection. 15 THE WITNESS: I -- can 16 you -- can I see the report, 17 please? I can't -- 18 BY MR. TISI: 19 Q. I will give it -- I will 20 give it to you. But you -- it was 21 provided to you. I saw it on your 22 supplemental reliance list that was 23 turned over to us last night. 24 Did you have that at the</p>	<p>1 A. They are two separate 2 reports. 3 Q. Okay. Now, Health Canada, 4 just for the record, is the Canadian 5 equivalent to the U.S. FDA? 6 A. That -- 7 MS. MILLER: Objection. 8 THE WITNESS: That's what 9 I've been told. I -- I don't 10 know. I didn't know one way or 11 the other. 12 BY MR. TISI: 13 Q. And other than for 14 litigation purposes, and I mean on both 15 sides, plaintiffs' experts and 16 defendants' experts, are you aware of any 17 more recent analysis of the causation 18 question through a Bradford Hill 19 framework than the one conducted by 20 Health Canada outside of litigation, are 21 you aware of anything else? 22 A. That's a long question. Do 23 you want to do -- I mean, I don't know -- 24 Q. Let me -- let me --</p>

22 (Pages 82 to 85)

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<p style="text-align: right;">Page 86</p> <p>1 A. -- because you're putting 2 Bradford Hill in there and -- 3 Q. Let me rephrase the question 4 then. 5 Do you know of any authors, 6 published or unpublished, apart from 7 litigation, which has done a causation 8 analysis of the question of ovarian 9 cancer and talc more recently than Health 10 Canada in December of 2018? 11 A. So the Health Canada report, 12 you mean, unpublished report, draft 13 report? 14 Q. Correct. 15 A. Has there been another 16 published study? 17 Q. Has there been any other 18 published or unpublished analysis of the 19 question of about whether ovarian cancer 20 and talcum powder products are linked, 21 is -- is that the most recent, outside of 22 litigation, that you can think of? 23 A. Oh, out -- 24 MS. MILLER: Objection.</p>	<p style="text-align: right;">Page 88</p> <p>1 BY MR. TISI: 2 Q. And in your -- in your 3 practice of -- in your professional 4 practice outside of litigation, is it 5 important for you to consider the 6 opinions and views of other scientists 7 who look at the same or similar questions 8 that you were asked to look at? 9 A. That's a really broad 10 question. 11 Q. Do you consider the views of 12 other scientists? 13 MS. MILLER: Objection. 14 THE WITNESS: When I do 15 research, I -- I look at 16 publications. So I believe those 17 probably are views of -- of other 18 scientists. I mean, to do 19 research, you -- you need to look 20 at the literature. 21 BY MR. TISI: 22 Q. Do you speak -- do you speak 23 to colleagues and get their opinions? 24 A. If we're doing research in</p>
<p style="text-align: right;">Page 87</p> <p>1 THE WITNESS: Outside of 2 litigation? I -- I don't know off 3 the top of my head. I'd have to 4 go through and look at all the 5 reports. 6 BY MR. TISI: 7 Q. Okay. Okay. I'm going to 8 have marked as Exhibit 4 a document which 9 is the draft screening assessment from 10 Health Canada. 11 Now, this is on the 12 supplemental reliance list that was 13 served on us last night, correct? 14 A. I -- 15 MS. MILLER: I don't think 16 she knows when it was served. 17 BY MR. TISI: 18 Q. Okay. Well -- all right. 19 You've seen this, correct? 20 A. I have seen this, correct. 21 Q. Okay. 22 (Document marked for 23 identification as Exhibit 24 Ballman-4.)</p>	<p style="text-align: right;">Page 89</p> <p>1 the same area, I may speak to a colleague 2 with respect to a research question I'm 3 working on. 4 Q. Do you go to meetings where 5 information is presented orally or on 6 posters? 7 A. I go to many meetings, and 8 so often there are information presented 9 orally and on posters. 10 Q. And on -- on the whole, the 11 views of other scientists is information 12 that you integrate into your knowledge 13 base when you look at scientific 14 questions, true? 15 MS. MILLER: Objection. 16 THE WITNESS: So it all 17 depends. It depends upon the 18 quality of -- of the data. I look 19 at the data. I -- I -- you know, 20 determine whether or not the 21 conclusions that they reach is -- 22 is justified by the data that they 23 have and their study design. And 24 so, I -- I -- you know, just</p>

23 (Pages 86 to 89)

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<p style="text-align: right;">Page 90</p> <p>1 because it's another scientist 2 doesn't necessarily mean... 3 BY MR. TISI: 4 Q. Now -- 5 MS. MILLER: We've been 6 going about an hour. Is this a 7 good time for a break or? 8 MR. TISI: Actually let me 9 finish this -- this area here. 10 BY MR. TISI: 11 Q. In -- the other report, I'm 12 going to talk about, you were involved in 13 the Viagra/Cialis litigation? 14 A. Yes. 15 Q. Okay. And you issued a 16 report in that litigation as well? 17 A. I did. 18 Q. You had a section in that 19 report dealing with regulatory issues and 20 the regulatory views of various European 21 and -- and U.S. agencies. Do you recall 22 that? 23 A. Can I see it, please? 24 Q. I don't have it with me,</p>	<p style="text-align: right;">Page 92</p> <p>1 Do you see that? 2 MS. MILLER: Objection. 3 It's not a study. It's a table. 4 BY MR. TISI: 5 Q. Do you see that? 6 A. I see a table that's titled 7 "Available Human Epidemiological Studies 8 Investigating the Association of Perineal 9 Talc and Ovarian Cancer." 10 Q. And as you glance through 11 these, the studies that are listed here, 12 these are studies that are familiar to 13 you, correct? 14 A. These look like they include 15 some of the case-control studies and 16 cohort studies that have been used in 17 other meta-analyses. 18 Q. Okay. They cover -- for 19 example, I see the Cramer study from 1982 20 that we marked? 21 A. I see that. 22 Q. Okay. And they cover 23 case-control studies, population-based 24 and hospital-based studies.</p>
<p style="text-align: right;">Page 91</p> <p>1 but -- but do you recall that, I'm asking 2 whether you recall -- 3 MS. MILLER: Objection. 4 THE WITNESS: No, I -- I 5 don't recall any specifics. 6 BY MR. TISI: 7 Q. Okay. 8 MS. MILLER: Give me time to 9 object, please. 10 Objection. 11 THE WITNESS: So, sorry. 12 BY MR. TISI: 13 Q. Let me ask you this. Go to 14 Page 16 -- 15 MS. MILLER: Of what? 16 MR. TISI: Of Exhibit 4. 17 BY MR. TISI: 18 Q. There's a Table 6.1. Do you 19 see that? 20 A. I do see the table. 21 Q. And it's a study entitled 22 "Available human epidemiologic studies 23 investigating the association of perineal 24 talc use and ovarian cancer."</p>	<p style="text-align: right;">Page 93</p> <p>1 Do you see that? 2 A. I see that study type is 3 listed. I don't know which are hospital 4 based and which are population based. 5 Q. And if -- if you look on 6 Page 18, it includes the cohort studies. 7 Do you see that? 8 A. Yes. I see page 18 lists 9 cohort studies. 10 Q. And they considered the 11 meta-analyses that you also looked at. 12 If you look at Page 16 under human 13 studies. It has the sentence, "Several 14 meta-analyses are available of the 15 epidemiologic data have been published, 16 some very recently. (Huncharek, 2003; 17 Langseth, 2008; Terry, 2018; Berge, 2018, 18 Penninkilampi and Eslick, 2018; Taher, 19 2018)." 20 Do you see that those? 21 A. I see that. I didn't 22 realize that Taher has been published. 23 Q. It's -- it's not been 24 published yet.</p>

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<p>1 A. But it says published.</p> <p>2 Q. Okay. So let me ask you</p> <p>3 this. Those are all studies that you're</p> <p>4 familiar with, correct? You've seen</p> <p>5 those?</p> <p>6 A. I have seen those studies.</p> <p>7 Q. All right. And so does it</p> <p>8 appear from looking at the studies, they</p> <p>9 considered pretty much -- they considered</p> <p>10 the same studies that you considered?</p> <p>11 A. I -- I -- I mean, I'd have</p> <p>12 to go through and look and compare</p> <p>13 whether or not every single study here is</p> <p>14 what every single study that I looked at.</p> <p>15 But I do -- it appears that, you know, I</p> <p>16 recognize the names of many of these</p> <p>17 studies here. I don't know if it's a</p> <p>18 complete match.</p> <p>19 Q. Okay. Now, can you turn to</p> <p>20 Page 19 through 21. On the very bottom</p> <p>21 of the page on 19 it has a section called</p> <p>22 "Strength"?</p> <p>23 A. Yes, I see that.</p> <p>24 Q. That's one of the Bradford</p>	<p>1 Q. Next page -- next paragraph</p> <p>2 says "Specificity." That's also a</p> <p>3 Bradford Hill aspect?</p> <p>4 A. I see where it says</p> <p>5 "specificity."</p> <p>6 Q. "Temporality" is also a</p> <p>7 Bradford Hill aspect?</p> <p>8 A. I see where it says --</p> <p>9 Q. Biologic gradient is also a</p> <p>10 Bradford Hill aspect?</p> <p>11 A. I see that.</p> <p>12 Q. Biologic plausibility?</p> <p>13 A. I see that section.</p> <p>14 Q. Coherence, they have that,</p> <p>15 correct?</p> <p>16 A. I see that section.</p> <p>17 Q. Okay. And all of those are</p> <p>18 the same -- that's the same framework</p> <p>19 that you used in your report, correct?</p> <p>20 You considered all those factors?</p> <p>21 A. I applied the Bradford Hill</p> <p>22 criteria when I looked at the totality of</p> <p>23 the data.</p> <p>24 Q. And those are the -- you</p>
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<p>1 Hill criteria, correct?</p> <p>2 A. Mm-hmm.</p> <p>3 Q. And if you look on the next</p> <p>4 page?</p> <p>5 A. Wait. I'm sorry. I don't</p> <p>6 know if this is actually referring to the</p> <p>7 Bradford Hill criteria. It just says</p> <p>8 "Strength."</p> <p>9 Q. Well, if you look at the</p> <p>10 sentence above, it says Hill criteria,</p> <p>11 1965, the paragraph directly above?</p> <p>12 A. Okay.</p> <p>13 Q. Okay. So if you look at the</p> <p>14 next page, Page 20, it talks --</p> <p>15 MS. MILLER: You're positing</p> <p>16 that strength means strength of</p> <p>17 association? Is that --</p> <p>18 MR. TISI: Yes, correct.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Okay. Next -- next page it</p> <p>21 has consistency. That's also a Bradford</p> <p>22 Hill criteria?</p> <p>23 A. I see where it says</p> <p>24 consistency.</p>	<p>1 applied those same factors from Bradford</p> <p>2 Hill that I just described, you looked</p> <p>3 at -- you looked at -- you looked at</p> <p>4 strength, consistency, specificity,</p> <p>5 temporality, biologic gradient, biologic</p> <p>6 plausibility, and coherence. You looked</p> <p>7 at all of those things, correct?</p> <p>8 A. When I evaluate the totality</p> <p>9 of the data, I did look at all the</p> <p>10 criteria of the Bradford Hill --</p> <p>11 Q. Okay. Now --</p> <p>12 A. -- framework.</p> <p>13 Q. If you go to Page 19 of 21</p> <p>14 of the report?</p> <p>15 MS. MILLER: Of her report</p> <p>16 or of the draft analysis?</p> <p>17 MR. TISI: Of the draft --</p> <p>18 MS. MILLER: Draft screening</p> <p>19 assessment?</p> <p>20 MR. TISI: Of Exhibit Number</p> <p>21 4.</p> <p>22 BY MR. TISI:</p> <p>23 Q. On Page 28 at the very</p> <p>24 top --</p>

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<p style="text-align: right;">Page 98</p> <p>1 A. So we're not on 21?</p> <p>2 MS. MILLER: You said 19 to</p> <p>3 21.</p> <p>4 MR. TISI: I'm actually</p> <p>5 moving through. 28 at the very</p> <p>6 top.</p> <p>7 BY MR. TISI:</p> <p>8 Q. You would agree with me that</p> <p>9 after discussing the Bradford Hill</p> <p>10 criteria or Bradford Hill analysis that</p> <p>11 we just talked about before, they say the</p> <p>12 following: "The meta-analyses of the</p> <p>13 available human studies in the</p> <p>14 peer-reviewed literature indicate a</p> <p>15 consistent and statistically significant</p> <p>16 positive association between perineal</p> <p>17 exposure to talc and ovarian cancer.</p> <p>18 Further available data are indicative of</p> <p>19 a causal effect."</p> <p>20 Do you see that?</p> <p>21 MS. MILLER: Objection. You</p> <p>22 said after the Bradford Hill?</p> <p>23 I'm confused.</p> <p>24 THE WITNESS: It's on 28.</p>	<p style="text-align: right;">Page 100</p> <p>1 dishonest, let's go back. They say it</p> <p>2 again, exactly after -- on Page 21, after</p> <p>3 the discussion of coherence. They say</p> <p>4 the most -- do you see where it says,</p> <p>5 "The most recent meta-analyses detailed</p> <p>6 above (Taher, 2018) and consistent with</p> <p>7 the Hill criteria, suggest a small but</p> <p>8 consistent statistically significant</p> <p>9 positive association between ovarian</p> <p>10 cancer and perineal exposure to talc.</p> <p>11 Further available data are indicative of</p> <p>12 a causal effect."</p> <p>13 Do you see that?</p> <p>14 A. I see the words on that</p> <p>15 page. But I'd like to point out that --</p> <p>16 Q. No. There's no question</p> <p>17 pending.</p> <p>18 MS. MILLER: Excuse me. I</p> <p>19 think she should be allowed to</p> <p>20 finish her statement.</p> <p>21 MR. TISI: I'd like to point</p> <p>22 out. No. I asked her if those</p> <p>23 were the words -- did I read that</p> <p>24 correctly. There's nothing more</p>
<p style="text-align: right;">Page 99</p> <p>1 MR. TISI: You don't need to</p> <p>2 be.</p> <p>3 Yes.</p> <p>4 BY MR. TISI:</p> <p>5 Q. So after having looked at</p> <p>6 the Bradford Hill criteria, or Bradford</p> <p>7 Hill aspects, they say the following:</p> <p>8 "The meta-analyses of available human</p> <p>9 studies in the peer-reviewed literature</p> <p>10 indicate a consistent and statistically</p> <p>11 significant positive association between</p> <p>12 perineal exposure to talc and ovarian</p> <p>13 cancer. Further available data are</p> <p>14 indicative of a causal effect."</p> <p>15 Do you see that?</p> <p>16 MS. MILLER: Objection.</p> <p>17 That's a dishonest question.</p> <p>18 BY MR. TISI:</p> <p>19 Q. You can --</p> <p>20 A. That's what's written on the</p> <p>21 page there. They do say that.</p> <p>22 Q. Okay. And they say it</p> <p>23 again. Actually, if you go back. Since</p> <p>24 counsel was saying that I was being</p>	<p style="text-align: right;">Page 101</p> <p>1 to say, Counsel.</p> <p>2 MS. MILLER: I think we're</p> <p>3 ready for a break. I asked for a</p> <p>4 break five minutes ago.</p> <p>5 MR. TISI: I am just -- I'm</p> <p>6 just going to mark an exhibit, and</p> <p>7 then we'll move on.</p> <p>8 I'm going to attach the --</p> <p>9 MS. MILLER: Why don't we</p> <p>10 just mark it after the break?</p> <p>11 MR. TISI: No, I'm going to</p> <p>12 mark it right now.</p> <p>13 THE WITNESS: I would really</p> <p>14 like a break soon.</p> <p>15 MR. TISI: We're going to</p> <p>16 take it as soon as I mark it.</p> <p>17 I'm going to mark the Health</p> <p>18 Canada conclusion that I read into</p> <p>19 the record on Page 28, and I'm</p> <p>20 going to mark that as Exhibit 5.</p> <p>21 MS. MILLER: I'm going to</p> <p>22 object to that.</p> <p>23 THE WITNESS: The Health</p> <p>24 Canada draft conclusion.</p>

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<p>1 BY MR. TISI: 2 Q. Yes. 3 A. And I don't see draft there. 4 Q. Okay. We can -- it says -- 5 MS. MILLER: Also, where 6 does it say "conclusion" in the 7 document? 8 BY MR. TISI: 9 Q. -- it actually says -- it 10 says draft screening assessment. 11 MS. MILLER: Actually, 12 conclusion would be this 13 (indicating). The conclusion is 14 what's on Page 29. So I object -- 15 MR. TISI: That's not -- you 16 could -- you could say what you -- 17 MS. MILLER: I object to 18 this -- 19 MR. TISI: You can object. 20 Object. 21 MS. MILLER: Okay. Let me 22 finish. 23 MR. TISI: Object. Fine. 24 MS. MILLER: You are not</p>	<p>1 exhibit. Here you go. 2 (Document marked for 3 identification as Exhibit 4 Ballman-5.) 5 THE VIDEOGRAPHER: Off the 6 record? Remove your microphone 7 please. The time is 10:10 a.m. 8 (Short break.) 9 THE VIDEOGRAPHER: We are 10 back on the record. The time is 11 10:25 a.m. 12 BY MR. TISI: 13 Q. Doctor, going back to 14 Exhibit Number 5, the Health Canada 15 statement. We'll call it a statement. 16 The -- they use the word 17 consistent. 18 Do you see that? 19 A. So when I read this 20 statement -- and it's also referring to 21 meta-analyses. And so it appears that 22 it's not just one meta-analysis. So -- 23 so they are saying that the meta-analyses 24 are consistent.</p>
Page 103	Page 105
<p>1 letting me finish my sentence, 2 sir. 3 MR. TISI: I don't need -- 4 object is fine. 5 MS. MILLER: No, it's not 6 fine. 7 I object to this exhibit, 8 because the Health Canada 9 conclusion is actually on Page 29 10 where it says conclusion -- 11 MR. TISI: That's the 12 regulatory -- that's the 13 regulatory conclusion. 14 MS. MILLER: This is not a 15 conclusion. 16 MR. TISI: Okay. 17 MS. MILLER: So that's a 18 false statement there. Health 19 Canada conclusion. 20 MR. TISI: That's fine. You 21 can -- 22 MS. MILLER: Okay. I think 23 we're ready for a break? 24 MR. TISI: That's an</p>	<p>1 Q. Okay. And the meta-analyses 2 are made up of all of the -- of all of 3 the observational studies, correct? 4 A. But the meta-analyses are 5 all analyzing essentially the same data. 6 They are reworking the same data. So it 7 would be strange if they would come up 8 with quite different results. 9 Q. So -- and they are all 10 consistent, correct? 11 A. But as I said, they are -- 12 they are analyzing exact same data in 13 essentially the same way. And so it 14 would be very strange if they didn't come 15 up with similar numbers. 16 Q. But you -- you think there 17 is no consistency, correct, your opinion 18 is there is no consistency in the 19 observational studies, correct, or is 20 there consistency? 21 MS. MILLER: Objection. 22 THE WITNESS: When I applied 23 the Bradford Hill, I state that I 24 feel that the consistency criteria</p>

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<p style="text-align: right;">Page 106</p> <p>1 was not met. 2 BY MR. TISI: 3 Q. Okay. And they say that 4 there was consistency shown when they 5 looked at the meta-analyses, correct? 6 A. Well, they are saying 7 meta-analyses are consistent. But as I 8 said, they keep -- meta-analyses, these 9 meta-analyses are essentially all 10 analyzing the same data. So reworking 11 the same data is like doing a 12 replication. So one would expect that 13 the numbers are similar. 14 Q. Well, the meta-analyses, 15 depending upon their time frame, did not 16 all use the same studies, did they? 17 A. They -- the earlier ones 18 used a subset of the studies used in the 19 later ones, because there were additional 20 studies done since when the earlier ones 21 were done. 22 Q. So they -- so they were not 23 all the same, correct? 24 A. Essentially though, I mean</p>	<p style="text-align: right;">Page 108</p> <p>1 MS. MILLER: Objection. 2 THE WITNESS: So I'm not 3 sure what available data they are 4 referring to, and being indicative 5 of a causal effect, this is -- is 6 taken out of context. I would 7 have to go back and -- and read 8 through the entire document. I 9 mean, I don't know what basis. I 10 don't know what data that that's 11 like being based upon. 12 BY MR. TISI: 13 Q. Well, we went through that, 14 Doctor. We went through and that's why I 15 took the time and showed you all the 16 studies that they looked at. And I -- I 17 showed you the Bradford Hill aspects that 18 they analyzed and they went through all 19 of that. 20 And based upon what they 21 looked at, okay, they concluded that the 22 totality of the evidence was indicative 23 of a causal effect, correct? 24 MS. MILLER: Objection.</p>
<p style="text-align: right;">Page 107</p> <p>1 in -- in statistics and in epidemiology, 2 you know, reworking data that are not 3 completely independent of each other, we 4 would expect similar results and 5 correlation. 6 Q. And they say, "Further 7 available data are indicative of a causal 8 effect." 9 Do you see that? 10 A. I -- I see what's stated 11 there. I -- I have no idea what that is 12 based upon. That -- I do see that 13 statement. 14 Q. And you disagree with that, 15 correct? 16 A. I -- I don't know if I agree 17 or disagree with it. 18 Q. So -- 19 A. I mean I -- I -- that's what 20 they wrote. I do agree with that. 21 Q. Okay. Do you agree that the 22 available data is indicative of a causal 23 effect or you disagree with the 24 Canadian -- the Canadian assessment here?</p>	<p style="text-align: right;">Page 109</p> <p>1 THE WITNESS: I think you 2 just -- that's a slightly 3 different question. 4 BY MR. TISI: 5 Q. Okay. 6 A. But we didn't look at all 7 the studies that they looked at in terms 8 of, we just went through and -- and I 9 quickly glanced and saw that they had a 10 category that said strength, they had a 11 category that said -- I didn't look 12 through carefully to see what exact 13 studies they looked at. 14 Q. Did you -- didn't you do 15 that when you were preparing for your 16 deposition today, didn't -- weren't you 17 interested to see how they reached this 18 conclusion which was different than 19 yours? 20 A. I -- you know, I glanced and 21 I read through the document as you noted. 22 I did not cite it in my report. 23 Q. Mm-hmm. 24 A. I -- it's just a draft. So</p>

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<p style="text-align: right;">Page 110</p> <p>1 it could change. And I didn't want --</p> <p>2 all my report is essentially based upon</p> <p>3 published literature. I didn't want to</p> <p>4 incorporate a draft of something that</p> <p>5 might change, and we don't know which way</p> <p>6 they may change due to all the comments</p> <p>7 they get. The -- I believe it's out for</p> <p>8 comment right now, so...</p> <p>9 Q. Well, that was -- that's</p> <p>10 going to be my question too.</p> <p>11 First of all, Health Canada</p> <p>12 is not involved in this litigation to</p> <p>13 your knowledge, is it?</p> <p>14 A. I have no idea one way or</p> <p>15 the other.</p> <p>16 Q. But you are, you are a paid</p> <p>17 witness, correct?</p> <p>18 A. I'm --</p> <p>19 MS. MILLER: Objection.</p> <p>20 BY MR. TISI:</p> <p>21 Q. You're a paid -- you've been</p> <p>22 paid for your -- the work you did on your</p> <p>23 report, correct?</p> <p>24 A. I am an expert witness for</p>	<p style="text-align: right;">Page 112</p> <p>1 know what I mean.</p> <p>2 THE WITNESS: I billed for</p> <p>3 \$56,000.</p> <p>4 BY MR. TISI:</p> <p>5 Q. And -- and that will --</p> <p>6 A. And I anticipate I will be</p> <p>7 paid.</p> <p>8 Q. Right. And -- and you have</p> <p>9 incurred additional time from the time of</p> <p>10 your last billing until today, correct?</p> <p>11 A. Yes, I have.</p> <p>12 Q. Okay. About how much time?</p> <p>13 A. Probably on the order, 20,</p> <p>14 30 hours.</p> <p>15 Q. Okay. And so would it be</p> <p>16 fair to say that as of today, you will</p> <p>17 ultimately bill anywhere between 75 and</p> <p>18 \$100,000?</p> <p>19 A. If the math works out.</p> <p>20 Q. Okay. And so you are a paid</p> <p>21 expert in this case, true?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I am being</p> <p>24 paid for my expert opinion.</p>
<p style="text-align: right;">Page 111</p> <p>1 Johnson & Johnson. I really haven't been</p> <p>2 paid yet. I'm still waiting for --</p> <p>3 sorry.</p> <p>4 Q. Okay. You are going to --</p> <p>5 well, I am sure -- I am sure Susan is</p> <p>6 good for her -- good for her word on</p> <p>7 that. I'm sure she will pay you</p> <p>8 imminently.</p> <p>9 A. Yes.</p> <p>10 Q. But -- but you have been</p> <p>11 paid anywhere between, up and through, I</p> <p>12 saw your bill, up and through -- it's</p> <p>13 \$56,000. But I assume you've billed</p> <p>14 since then.</p> <p>15 How much have you --</p> <p>16 MS. MILLER: Objection. She</p> <p>17 just said she hasn't been paid,</p> <p>18 and you just said you have been</p> <p>19 paid.</p> <p>20 MR. TISI: Fine. I'm not --</p> <p>21 I'm not quibbling with you.</p> <p>22 MS. MILLER: Well, I mean,</p> <p>23 but just --</p> <p>24 MR. TISI: You know -- you</p>	<p style="text-align: right;">Page 113</p> <p>1 BY MR. TISI:</p> <p>2 Q. Okay. Now, would you agree</p> <p>3 with me -- let me put it this way. You</p> <p>4 would not write this -- you do not agree</p> <p>5 based upon your analysis of the evidence,</p> <p>6 with the statement in Exhibit Number 5</p> <p>7 from Health Canada. You would disagree</p> <p>8 with that, true?</p> <p>9 MS. MILLER: Objection.</p> <p>10 Asked and answered twice.</p> <p>11 MR. LOCKE: And I just want</p> <p>12 to assert an objection. I don't</p> <p>13 believe -- I believe there are</p> <p>14 words italicized here that are not</p> <p>15 italicized in the original.</p> <p>16 MR. TISI: And that's fine.</p> <p>17 You're exactly right, Tom.</p> <p>18 BY MR. TISI:</p> <p>19 Q. So I will make a</p> <p>20 representation I -- that I italicized</p> <p>21 those because I was going to ask you</p> <p>22 questions about those. But the record</p> <p>23 will reflect that those are not</p> <p>24 italicized in the original.</p>

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<p style="text-align: right;">Page 114</p> <p>1 That being the case, you 2 would not write the statement that Health 3 Canada did because you do not believe 4 that the data as a whole that you looked 5 at was indicative of a causal effect? 6 MS. MILLER: Objection. 7 THE WITNESS: Again, you 8 know, this is taken out of their 9 report at some section, and as we 10 discussed I believe it's not even 11 in their conclusions. And I -- I 12 don't know -- I mean, I wrote in 13 my expert report what I wrote. So 14 I don't have a statement in my 15 expert report that says this. 16 BY MR. TISI: 17 Q. And you would disagree with 18 that -- those statements, correct? 19 A. I just -- 20 MS. MILLER: Objection. 21 THE WITNESS: I just looked 22 at the data as a whole and did my 23 analyses and came up with the 24 conclusion that I came up with.</p>	<p style="text-align: right;">Page 116</p> <p>1 looked at are indicative of a causal 2 effect? 3 A. So it is my professional 4 opinion that there's no evidence of a 5 causal relationship between perineal or 6 genital talcum powder exposure and 7 ovarian cancer. 8 Q. So you do not think there's 9 a causal effect? 10 A. That is my opinion. 11 Q. Okay. So -- and Health 12 Canada, at least as of today, has a 13 contrary view, true, subject to your view 14 that they may change? But as of today, 15 they have a different view based upon 16 their analysis of the Bradford Hill 17 criteria, true? 18 MR. LOCKE: Objection. 19 MS. MILLER: Objection. 20 THE WITNESS: Yeah, I -- 21 I -- I would have to again read 22 through this carefully. 23 BY MR. TISI: 24 Q. Okay.</p>
<p style="text-align: right;">Page 115</p> <p>1 Again, this is a draft. I 2 mean, I -- yeah. 3 BY MR. TISI: 4 Q. So your conclusion -- 5 A. I don't agree or disagree. 6 I'm just saying that -- 7 Q. So you don't disagree with 8 this? 9 A. I said I don't agree or 10 disagree. And I'm saying that when I 11 look at the science and I did my 12 analyses, I have put forward my 13 conclusion. 14 I obviously -- you know, 15 even if I believed what they did, I would 16 probably not have the exact same words. 17 That would be plagiarism. 18 Q. But you would just -- okay. 19 Let me ask you this statement. Let me 20 ask you the question directly. 21 Do you believe that the data 22 are indicative of a causal effect, 23 irrespective of this statement? Do you 24 believe that the data as a whole that you</p>	<p style="text-align: right;">Page 117</p> <p>1 A. I would agree that they did 2 not write a sentence exactly the way I 3 wrote a sentence there. 4 You know, again, I'd have to 5 read through this carefully to make sure 6 that this -- this -- this excerpt here 7 reflects the entirety of their analyses 8 and their opinions. 9 Q. Well, it's not unusual, 10 Doctor, for experts in epidemiology to 11 disagree on issues of causation when they 12 do their analysis, true? 13 A. It depends. 14 Q. Okay. Well, in many -- you 15 know, there are experts -- in fact, you 16 mention it in your report that some 17 experts believe that ovarian cancer -- 18 some people believe that ovarian cancer 19 can be caused by talcum powder; other 20 people don't. That's not unusual; is 21 that true? 22 A. So when I did my analyses 23 and looked at the data, I don't think 24 there's any scientific basis for any</p>

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<p>1 other opinion that there is no evidence, 2 credible evidence, of a causal 3 relationship between -- 4 Q. That is not my question. 5 You know, honestly, at some point I 6 really am going to have to call the 7 judge. 8 My question to you is, it is 9 not unusual for experts in epidemiology 10 to look at the same data and come to 11 different conclusions, true? 12 MS. MILLER: Please let her 13 finish her answer without -- 14 MR. TISI: Well, I'm not -- 15 I'm not going to sit -- 16 MS. MILLER: She was in the 17 middle of a sentence. 18 MR. TISI: I'm not -- I am 19 not going to sit here and listen 20 to her filibuster. I'm not going 21 to do it. 22 MS. MILLER: She's not 23 filibustering. She's answering 24 the question. You're trying to</p>	<p>1 and filibuster -- 2 MS. MILLER: She's not 3 filibustering. You're trying to 4 put words in her mouth. She is 5 trying to answer as an 6 epidemiologist from her scientific 7 experience, and you're trying to 8 put words in her mouth for sound 9 bytes you want. And you're 10 frustrated because she's trying to 11 give you honest, complete answers 12 as an epidemiologist. 13 MR. TISI: Oh, that's so 14 good of you. I'm so -- I'm so 15 glad that you said that. 16 BY MR. TISI: 17 Q. So, Doctor, in epidemiology, 18 cancer, cancer with cigarettes, for a 19 long time there was a debate in the 20 scientific community about whether 21 cigarettes cause cancer, true? 22 A. I haven't looked at that 23 literature in depth. I mean, possibly. 24 I mean, I'd have to --</p>
Page 119	Page 121
<p>1 put words in her mouth. 2 MR. TISI: I am not -- I'm 3 allowed -- 4 MS. MILLER: You're trying 5 to put words -- can you let me 6 finish my sentence? 7 MR. TISI: No, actually 8 yours -- 9 MS. MILLER: You're not 10 going to let me finish my 11 sentence? 12 MR. TISI: You're limited to 13 "objection." That's what you're 14 limited to in this deposition. 15 MS. MILLER: I think that if 16 you're not allowing -- 17 MS. SHARKO: I don't think 18 that's true. 19 MS. MILLER: -- the witness 20 to finish her sentences. I am 21 allowed to speak. And if you want 22 to call the judge, I am happy to. 23 MR. TISI: If your -- if 24 your witness is going to sit here</p>	<p>1 Q. Okay. It's not unusual in 2 the field of epidemiology for experts in 3 epidemiology to look at data and reach 4 different conclusions in their 5 professional judgment, true? 6 MS. MILLER: Objection. 7 THE WITNESS: So again, I -- 8 all I can say is I looked at the 9 data in its totality. I did the 10 analyses and wrote the report with 11 all sort of my methodology and how 12 I arrived at the opinions. And I 13 do not believe there's scientific 14 credible evidence that there is a 15 causal relationship between 16 talcum -- perineal talcum powder 17 exposure and ovarian cancer. To 18 me, that's the -- 19 BY MR. TISI: 20 Q. So, all right. 21 That wasn't my question. 22 And my question was a general question. 23 Having -- I'm going to take 24 talcum powder products out of -- out of</p>

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<p style="text-align: right;">Page 122</p> <p>1 the equation now. So you don't have to 2 answer me the question about what you did 3 in talc. Okay. 4 Is it not a true statement 5 that in general, epidemiologists when 6 looking at a causation question, can look 7 at the same data and reach different 8 conclusions? Does that not happen? 9 MS. MILLER: Objection. 10 THE WITNESS: I think it has 11 to depend upon what the question 12 is of interest and what level of 13 data are available. I mean, I 14 cannot answer that question 15 without knowing more specifics. 16 BY MR. TISI: 17 Q. Have you responded -- you 18 said there's a comment period. The 19 comment period was from December 6th 20 through February 6th. 21 Did you respond to 22 comment -- do you feel -- I gather you 23 feel strongly about your opinions, 24 correct?</p>	<p style="text-align: right;">Page 124</p> <p>1 again? 2 Q. Would you agree with me that 3 whether or not talcum powder products 4 cause ovarian cancer, the question you're 5 here to answer for us today, is an 6 important public health issue? 7 A. I believe what's an 8 important public health issue is -- is 9 trying to reduce the mortality from 10 ovarian cancer. 11 Q. Okay. And the question -- 12 you understand that there's been a debate 13 in the medical and scientific community 14 for decades on the question of whether or 15 not talcum powder products cause ovarian 16 cancer, correct? 17 MS. MILLER: Objection. 18 BY MR. TISI: 19 Q. IARC addressed it. FDA 20 addressed it. Health Canada addressed 21 it. It's been in the published 22 literature. You would agree with me on 23 that, right? 24 MS. MILLER: Are you asking</p>
<p style="text-align: right;">Page 123</p> <p>1 A. I don't know if I feel 2 strongly or not. I would say that I -- I 3 believe my opinions are based upon the 4 science. 5 Q. Well, you would agree with 6 me that ovarian cancer is a serious 7 disease? 8 A. It kills women. It's a 9 serious disease. 10 Q. Okay. And you would agree 11 with me that the mortality involved in 12 ovarian cancer is very, very high? 13 A. I -- I know that there are 14 different subtypes of ovarian cancer and 15 I -- the high grade serous has -- has -- 16 is not a very good prognosis. I agree a 17 lot of people die from it. 18 Q. And would you agree that 19 whether or not, irrespective of your view 20 of the evidence, whether or not talcum 21 powder products can cause ovarian cancer, 22 would be an important public health 23 issue? 24 A. What -- could you ask that</p>	<p style="text-align: right;">Page 125</p> <p>1 the last question that I objected 2 to or have you changed your 3 question? 4 BY MR. TISI: 5 Q. I'm asking you the question 6 I asked. You -- 7 MS. MILLER: Which? 8 BY MR. TISI: 9 Q. You understand that various 10 agencies have looked at this question, 11 that there has been a debate in the 12 medical and scientific community as to 13 the meaning of the science on ovarian 14 cancer and talc, true or not true? 15 MS. MILLER: Objection. 16 THE WITNESS: There is 17 different parts in there. What 18 I -- I would say is IARC looked at 19 the question. I'm not sure how 20 deeply the FDA has looked at it. 21 And I know that there's a draft 22 Health Canada document at this 23 point. So those agencies have 24 done something with respect to</p>

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<p style="text-align: right;">Page 126</p> <p>1 this. 2 BY MR. TISI: 3 Q. And you agree that the -- 4 the questions that they are wrestling 5 with is an important one? 6 MS. MILLER: Objection. 7 THE WITNESS: Important in 8 what sense? 9 BY MR. TISI: 10 Q. Important public health 11 question. They are addressing an 12 important public health question. 13 A. If -- if there were evidence 14 that there was a causal relationship 15 between perineal and genital talcum 16 exposure and ovarian cancer, if there was 17 evidence that that is the case, then it 18 would translate into a public -- probably 19 a considerable public health. 20 Q. Okay. And you feel strongly 21 about your opinion that there is no such 22 evidence, true? 23 A. Again, my -- I don't -- I 24 don't know how to use that word strongly.</p>	<p style="text-align: right;">Page 128</p> <p>1 Representatives held hearings on talc and 2 causation. Do you know that? 3 A. I did not know that. 4 Q. Do you know that one of the 5 epidemiologists, Dr. McTiernan, you know 6 her? 7 A. I know the name. 8 Q. Okay. You know she appeared 9 at that hearing. Do you know anything 10 about that? 11 A. Again, I -- I wasn't aware 12 of the hearing so I do not know. I -- so 13 I wouldn't know that she appeared. 14 Q. Did J&J ask you, say, you 15 know, Dr. Ballman, you're an expert in 16 the field of analyzing causation from an 17 epidemiology standpoint, would you 18 represent us before the House of 19 Representatives on this important 20 question? 21 MS. MILLER: Objection. 22 THE WITNESS: I was not 23 contacted by J&J to appear in a 24 congressional.</p>
<p style="text-align: right;">Page 127</p> <p>1 I believe that my evidence 2 is -- my statement is based upon my 3 scientific analyses of the data in 4 total -- 5 Q. Have you shared -- 6 A. -- and is supported. 7 Q. I apologize. 8 Were you -- did you share 9 that -- your opinions with Health Canada? 10 A. I did not. 11 Q. Okay. Did you -- have you 12 tried to contact the FDA? 13 A. I have not done that. 14 Q. Have you contacted the 15 National Cancer Institute to tell them 16 there's no problem? 17 MS. MILLER: Objection. 18 THE WITNESS: I -- I 19 wouldn't know who to contact. I 20 don't even know if there's such a 21 mechanism to do so. 22 BY MR. TISI: 23 Q. Okay. Well, you know last 24 week the United States House of</p>	<p style="text-align: right;">Page 129</p> <p>1 BY MR. TISI: 2 Q. Have you presented your 3 opinions on the subject to your medical 4 and scientific colleagues at Weill 5 Cornell? 6 MS. MILLER: Objection. 7 THE WITNESS: I have not 8 discussed this with my colleagues 9 at Weill Cornell. 10 BY MR. TISI: 11 Q. I mean, there are -- you 12 have an oncology division, and a 13 gynecology division at Weill Cornell I 14 assume? 15 A. I'm not sure what their 16 terms are. But there is a group that 17 works on gynecology -- gynecology 18 issues -- gynecology, and there is a 19 hem/onc. And I don't know if they are 20 divisions or departments, that sort of 21 thing. 22 Q. Have you reached out to them 23 and said to -- to any of them, gee, you 24 know, I have done this causation</p>

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<p style="text-align: right;">Page 130</p> <p>1 analysis, and, you know, you really could 2 tell women they can use talcum powder 3 products everyday for the next 40 years 4 and it be not be a problem in terms of 5 increasing their risk for ovarian cancer. 6 MS. MILLER: Objection. 7 BY MR. TISI: 8 Q. Have you done that? 9 MS. MILLER: Objection. 10 THE WITNESS: I -- I have 11 not contacted any -- I have not 12 discussed this with -- with any 13 one of my colleagues. 14 BY MR. TISI: 15 Q. If -- if one of your 16 colleagues at Weill Cornell, your 17 oncology colleagues, came up to you and 18 said look, I heard you were involved in 19 the -- looking at talcum powder products 20 and ovarian cancer for the -- in the 21 litigation involving Johnson & Johnson, 22 you've done your analysis, do you think 23 it's okay if I tell my patients that they 24 can dust everyday for the next 30 years</p>	<p style="text-align: right;">Page 132</p> <p>1 that -- that that -- that that 2 issue has been raised, that -- 3 that -- I don't know who is saying 4 that there may be asbestos in 5 talcum powder. 6 BY MR. TISI: 7 Q. So you have not reviewed 8 evidence in this case that asbestos may 9 or may not be in the talcum powder 10 products that Johnson & Johnson sold? 11 MS. MILLER: Objection. 12 THE WITNESS: So I believe 13 my opinion -- my -- not believe. 14 But my opinion is based upon 15 talcum powder, whatever it's 16 composed of. So I don't know 17 what's in it. But talcum powder, 18 whatever it's composed of, I don't 19 find any evidence -- or credible 20 evidence that there's a causal 21 relationship. 22 BY MR. TISI: 23 Q. Well, if there was asbestos 24 in talcum powder products, would you, if</p>
<p style="text-align: right;">Page 131</p> <p>1 and it won't increase the risk? 2 MS. MILLER: Objection. 3 THE WITNESS: I -- I would 4 say it's my professional opinion 5 that there's no evidence of a 6 causal relationship between 7 perineum-talcum powder exposure 8 and ovarian cancer. 9 I'm not a gynecologist. So 10 I would not presume to tell a 11 gynecologist what they should tell 12 their patients with -- with 13 respect to anything. 14 BY MR. TISI: 15 Q. Now, you do understand that 16 in this case there is an allegation that, 17 among other things, that talcum powder 18 products used by -- manufactured and sold 19 by J&J contained asbestos. Have you seen 20 that? 21 MS. MILLER: Objection. 22 THE WITNESS: I think I saw 23 somewhere in the media, it might 24 have been a tweet or something,</p>	<p style="text-align: right;">Page 133</p> <p>1 that same oncologist at Weill Cornell 2 came up to you and said Dr. -- 3 Dr. Ballman, I know that you are involved 4 in litigation. You've looked at the 5 causation question. If there is asbestos 6 in the talcum powder that my patients 7 use, is that okay for her to dust every 8 day? What would you tell them? 9 MS. MILLER: Objection. 10 THE WITNESS: I would say 11 the same thing I answered to the 12 talcum powder question, because I 13 analyze whether or not there's 14 evidence of a causal relationship 15 between talcum powder -- whatever 16 is in it -- I have no idea what's 17 in it -- causes ovarian cancer. 18 And so I would say that 19 that's my opinion. And again I 20 would not presume to tell a 21 gynecologist what they should tell 22 their patients one way or another, 23 because I am not an M.D. 24 BY MR. TISI:</p>

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<p style="text-align: right;">Page 134</p> <p>1 Q. Well, one of the -- one of 2 the aspects of Bradford Hill -- and we're 3 going to talk about this -- is the issue 4 of biologic plausibility, correct? 5 A. That is one of the criteria 6 within the Bradford Hill framework. 7 Q. If -- I'm going to ask you 8 to assume for the purposes of my question 9 that talcum powder products -- you would 10 agree with me that asbestos is a 11 carcinogen, correct? 12 MS. MILLER: Objection. 13 THE WITNESS: I have not 14 looked into the talcum powder data 15 and literature. So I only know 16 that there seems to be a strong 17 association that increases the 18 risk of mesothelioma, so a risk 19 factor for sure, between asbestos 20 exposure and mesothelioma. 21 BY MR. TISI: 22 Q. And looking at the issue of 23 whether or not there's a biologically 24 plausible explanation for the</p>	<p style="text-align: right;">Page 136</p> <p>1 me -- let me ask you this way. Let me 2 give you a hypothetical. Let me withdraw 3 the question. 4 Okay. If we had a bottle, 5 and the bottle was full of asbestos and 6 nothing else. Would you tell -- would 7 you tell a woman that she could use it to 8 dust her perineal -- her perineum? 9 MS. MILLER: Objection. I 10 think she said -- 11 MR. TISI: I don't -- I 12 don't care what you think she 13 said. Objection. 14 MS. MILLER: You've asked 15 this question 100 times. 16 MR. TISI: I'm asking -- I'm 17 asking -- 18 MS. MILLER: She said she 19 doesn't give advice. 20 MR. TISI: She's not. I'm 21 asking -- I'm asking you a 22 hypothetical. 23 BY MR. TISI: 24 Q. If -- if I had a bottle of</p>
<p style="text-align: right;">Page 135</p> <p>1 increased -- an association, would the 2 presence of a carcinogen be important to 3 look at? 4 A. So looking at biological 5 plausibility, what would be important is 6 that in the biological experiments that 7 are done, that they use talcum powder, 8 the same type of talcum powder that women 9 use, to see if that talcum powder leads 10 to transformation in animals, let's say, 11 to ovarian cancer. 12 Q. But if one of the components 13 was a known carcinogen, wouldn't that be 14 a plausible explanation for the 15 association seen in the meta-analyses? 16 MS. MILLER: Objection. 17 THE WITNESS: Again, I mean, 18 the question isn't asbestos. The 19 question is whether talcum powder, 20 however it's composed -- 21 BY MR. TISI: 22 Q. And if it's composed 23 partially of asbestos, if it's composed 24 partially of asbestos -- let me -- let</p>	<p style="text-align: right;">Page 137</p> <p>1 pure asbestos, would that be a 2 biologically -- let me -- let me give you 3 a different hypothetical. 4 MS. MILLER: Are you 5 striking the question? 6 MR. TISI: Yes, I am, 7 Counsel. 8 BY MR. TISI: 9 Q. If I had five epidemiology 10 studies all showed an increased risk of 11 ovarian cancer and asbestos, and I had a 12 bottle of asbestos, would you say that 13 that would be okay to dust on the 14 perineum? 15 MS. MILLER: Objection. 16 THE WITNESS: So that's 17 difficult. First of all, I would 18 want to know what the five 19 epidemiology studies are, if there 20 are, you know, observational 21 studies. I mean, I don't know. 22 I would need to know the 23 dose. The dose makes the poison. 24 I don't know. I did not do any</p>

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<p style="text-align: right;">Page 138</p> <p>1 study on asbestos, so I wouldn't 2 render an opinion to a woman what 3 she should or should not use in 4 general either. 5 BY MR. TISI: 6 Q. Would you tell a family -- 7 would you tell a family member it's okay 8 to dust with asbestos? 9 MS. MILLER: Please stop 10 interrupting her answers, please. 11 BY MR. TISI: 12 Q. Would you tell a family 13 member that it's okay to dust with 14 asbestos? 15 A. Yeah, again, this is a 16 hypothetical. 17 Q. Absolutely. 18 A. I mean, you know, I -- I 19 wouldn't say -- I -- I wouldn't say one 20 way or the other. I would have to look 21 at the literature and see sort of whether 22 or not that that would be -- I don't know 23 asbestos. And so that's why I'm having a 24 hard time answering this question.</p>	<p style="text-align: right;">Page 140</p> <p>1 I can't imagine why anyone would dust 2 with asbestos. So my question -- my 3 second question would be, if the bottle 4 was half asbestos and half talc, would 5 you say that that would be okay? 6 MS. MILLER: Objection. 7 THE WITNESS: So my -- what 8 I was going to try to finish in 9 the last one is, it would be like 10 if it were something -- if it were 11 full of cinnamon and someone came 12 to me and said, can I dust with 13 cinnamon? I mean, why would you 14 want to dust with cinnamon. I -- 15 I mean, that's a weird question to 16 me. 17 BY MR. TISI: 18 Q. And so the question -- why 19 would you want to dust with asbestos, 20 right? 21 A. Well, I -- you know, I'm not 22 seeing a purpose for doing it. 23 Q. I'm asking you from a 24 safety -- from a safety perspective.</p>
<p style="text-align: right;">Page 139</p> <p>1 Q. Okay. So just the record is 2 clear, if I had a bottle of asbestos and 3 you were advising a family member and a 4 family member came to you and said, 5 "Dr. Ballman, do you think it's okay if I 6 dust with asbestos," you wouldn't know 7 what answer to give? You'd say I have to 8 take out the literature and look at it? 9 MS. MILLER: Objection. 10 Maybe -- you don't need to have 11 those facial expression. 12 THE WITNESS: I mean, that's 13 a real hypothetical, because I 14 couldn't imagine anyone coming to 15 me and saying can they dust with 16 asbestos. So that's why I'm 17 having a hard time answering this 18 question. I just don't see any -- 19 any -- what would be the purpose 20 of dusting with asbestos? What 21 would be the -- I just don't -- 22 BY MR. TISI: 23 Q. Honestly I can't imagine 24 either. So let me ask you the question.</p>	<p style="text-align: right;">Page 141</p> <p>1 Let's assume there was a purpose -- I'm 2 going to add to my hypothetical. 3 Let's assume there was a 4 purpose to do it, and somebody came up to 5 you and said, "I think it's -- I think 6 I'd like to dust with asbestos." 7 Would you say that that 8 would be okay? 9 MS. MILLER: Objection. 10 THE WITNESS: I just can't 11 imagine that situation. 12 BY MR. TISI: 13 Q. Okay. 14 A. So it's very -- I can't 15 answer that. 16 Q. I'm asking -- bear with me 17 in the hypothetical. We're allowed to do 18 that in a deposition. 19 If -- if -- if there were a 20 reason and somebody came up to you and 21 asked you for advice. Would you say to 22 them, sure, dust with asbestos? 23 MS. MILLER: Objection. 24 THE WITNESS: So, what I</p>

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<p style="text-align: right;">Page 142</p> <p>1 feel comfortable in saying, and 2 this is what I addressed, is if 3 that cup were full of talcum 4 powder and someone really would 5 have asked my opinion as to 6 whether or not they should use it, 7 I would just say it's my 8 professional opinion that, you 9 know, whatever is in there, you 10 know, that's no causal 11 relationship between dusting on 12 the perineum and ovarian cancer. 13 BY MR. TISI: 14 Q. Okay. And that would 15 include, whatever in there, if there is 16 asbestos in there? 17 A. Well, whatever talcum 18 powder, that's the literature I looked 19 at, whatever that talcum powder is 20 composed of, there is no evidence that 21 it -- credible evidence that it causes 22 ovarian cancer. 23 Q. Let me switch topics again. 24 Go to Exhibit Number 1,</p>	<p style="text-align: right;">Page 144</p> <p>1 A. Unless new information comes 2 to light. 3 Q. Okay. Does it fully 4 describe the methodology that you use to 5 reach your opinions? 6 A. I -- I don't know what you 7 mean by fully. But I do explain the 8 methodology that I used and -- and 9 provide bases for why I come to 10 conclusions. 11 Q. Did you grade the evidence 12 giving numerical values? Did you say, 13 well, this is a four on a scale of five, 14 this is a two on a scale of five, you 15 didn't do that, right? 16 A. Grade what evidence? 17 Q. Any of the evidence you 18 used. Did you provide -- in weighing the 19 evidence, did you grade them? 20 MS. MILLER: Objection. 21 BY MR. TISI: 22 Q. Did you provide any 23 numerical values? 24 A. I'm -- I'm confused by the</p>
<p style="text-align: right;">Page 143</p> <p>1 which is the report you were going to -- 2 you gave. 3 A. Yes, I'm there. 4 Q. Okay. Front page says -- 5 I'm sorry, let me -- let me just -- you 6 signed that page, correct? 7 A. Yes. 8 Q. Was every talc-specific 9 opinion contained in this report reached 10 after meeting with the J&J lawyers? 11 MS. MILLER: Objection. 12 This has been addressed already 13 before. 14 BY MR. TISI: 15 Q. Yeah, okay. 16 A. This -- this entire report 17 and all the research done for this report 18 was done after I started working on 19 this -- well, I did it as part of 20 generating this report which happened 21 after November 2018. 22 Q. Does the report give all the 23 opinions you're prepared to give in this 24 case?</p>	<p style="text-align: right;">Page 145</p> <p>1 question. I mean, when one does 2 research, it's not common to grade every 3 piece of data that's on hand in any -- 4 any way. So I'm not sure. So I -- I 5 think I don't understand your question. 6 Q. Thank you. I appreciate 7 that. 8 Now, we discussed this 9 before, but you employed what are called 10 the Bradford Hill analysis, correct? 11 A. Something along those terms. 12 Q. Okay. 13 MR. TISI: And for the 14 record, I want to attach as 15 Exhibit Number 6 Dr. Hill's 16 article. 17 (Document marked for 18 identification as Exhibit 19 Ballman-6.) 20 BY MR. TISI: 21 Q. Is this the article, 1965 22 article that you were referring to in 23 your report? 24 A. Yes.</p>

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<p>1 Q. Thank you.</p> <p>2 Is this a -- is it fair to</p> <p>3 say that in the field of epidemiology, as</p> <p>4 you understand it, this is a seminal --</p> <p>5 seminal analysis of how to do a causation</p> <p>6 analysis?</p> <p>7 A. I would say it -- it</p> <p>8 provides the framework for how</p> <p>9 epidemiologists go about in determining</p> <p>10 whether there is a causal relationship.</p> <p>11 Q. And while there are a lot of</p> <p>12 published articles out there, you would</p> <p>13 consider this to be a fairly important</p> <p>14 piece of -- this would be, you know, kind</p> <p>15 of a different category in terms of its</p> <p>16 impact on how we look at causation</p> <p>17 questions?</p> <p>18 A. Again, I think I -- I would</p> <p>19 say it sort of frames today how -- how</p> <p>20 people evaluate causation questions.</p> <p>21 It's -- it's the first basis of it.</p> <p>22 Q. When is -- prior to meeting</p> <p>23 with the lawyers in this case, had you</p> <p>24 ever seen the Hill criteria -- had you</p>	<p>1 keep piling question -- objection.</p> <p>2 I'd like to say something.</p> <p>3 You keep piling question</p> <p>4 upon question upon question so --</p> <p>5 MR. TISI: Objection is --</p> <p>6 MS. MILLER: Okay.</p> <p>7 MR. TISI: Objection is</p> <p>8 fine, Counsel.</p> <p>9 MS. MILLER: And I think</p> <p>10 it -- it's impossible for her to</p> <p>11 know which question to answer. I</p> <p>12 don't think it's fair.</p> <p>13 MR. TISI: How about the</p> <p>14 last one?</p> <p>15 Well, when she looks at</p> <p>16 me --</p> <p>17 THE WITNESS: Can you repeat</p> <p>18 the last one, please?</p> <p>19 MR. TISI: Yes.</p> <p>20 MS. MILLER: Can you just</p> <p>21 try to ask one question at a time.</p> <p>22 That's all I ask.</p> <p>23 BY MR. TISI:</p> <p>24 Q. Is -- is there -- is there</p>
Page 147	Page 149
<p>1 ever seen the Hill article?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And is the Hill</p> <p>4 criteria applied any differently</p> <p>5 depending upon where you live?</p> <p>6 In other words, do -- do</p> <p>7 people in France apply the Hill criteria</p> <p>8 the same way they apply it in the United</p> <p>9 States?</p> <p>10 MS. MILLER: Objection.</p> <p>11 BY MR. TISI:</p> <p>12 Q. People in England apply it</p> <p>13 the same way they apply it in Canada?</p> <p>14 MS. MILLER: Is that -- is</p> <p>15 that --</p> <p>16 BY MR. TISI:</p> <p>17 Q. I'm -- I'm asking you</p> <p>18 geographically. Is there -- if anyone</p> <p>19 were to stand up in court and say well,</p> <p>20 you know, this is an English scientist</p> <p>21 and, therefore, they apply it differently</p> <p>22 in England than they apply it in the</p> <p>23 United States.</p> <p>24 MS. MILLER: I think you</p>	<p>1 any --</p> <p>2 MS. MILLER: I'll object</p> <p>3 less that way.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Is there any difference</p> <p>6 between how scientists approach a</p> <p>7 causation question depending upon where</p> <p>8 they happen to live and practice?</p> <p>9 A. I believe that</p> <p>10 epidemiologists apply this criteria. I</p> <p>11 have no evidence that it would be</p> <p>12 dependent upon geographic location of --</p> <p>13 of the epidemiologist.</p> <p>14 Q. Okay. And so for example,</p> <p>15 we use the issue, we -- we looked at the</p> <p>16 Health Canada report before. You have no</p> <p>17 reason to believe that they apply the --</p> <p>18 the Bradford Hill criteria different in</p> <p>19 Canada than they do in the United States?</p> <p>20 A. I -- I think any good</p> <p>21 epidemiologist would -- would apply</p> <p>22 scientifically based methods to -- to</p> <p>23 come up with their conclusions.</p> <p>24 Q. Okay. And certainly the</p>

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<p style="text-align: right;">Page 150</p> <p>1 Hill framework is a scientifically based 2 framework for looking at causation? 3 A. It provides a framework in 4 which people can look at -- at the issue 5 of causation. 6 Q. Okay. Did you write your 7 general causation report Exhibit 1? 8 A. I wrote everything in it 9 except for -- title. Except for the 10 materials reviewed and considered piece. 11 Q. Okay. And are all the words 12 and sentences in the report yours? 13 A. I -- I wrote the entire 14 report. 15 Q. Did the lawyers for J&J 16 write any of the words and sentences 17 contained in your report? 18 A. I -- I wrote the entire 19 report. 20 Q. When did you actually start 21 to write the report? 22 A. From the beginning, 23 essentially. Because as I was reviewing 24 the literature, I -- I put sections into</p>	<p style="text-align: right;">Page 152</p> <p>1 expert witness? Have you told anybody 2 that? 3 MS. MILLER: Objection. 4 THE WITNESS: Have I told 5 someone that it -- 6 BY MR. TISI: 7 Q. Have you ever told anybody, 8 you know, being an expert witness I can 9 make a little extra money, or words to 10 that effect? 11 MS. MILLER: Objection. 12 THE WITNESS: Not that I 13 recall. 14 BY MR. TISI: 15 Q. If you go to Page 21 of your 16 report -- actually, let me change it. 17 You rely on the -- you look 18 at the observational studies and 19 evidence, correct? 20 A. I -- I -- I looked at 21 observational studies as part of my 22 analyses. 23 Q. And in addition you looked 24 at the biologic evidence and that's on</p>
<p style="text-align: right;">Page 151</p> <p>1 a document that was the basis of my 2 report. 3 Q. When did you first start 4 becoming an expert witness? I know you 5 were involved in the Viagra case and I -- 6 When did you -- when did you 7 first make yourself available as an 8 expert witness in litigation? 9 MS. MILLER: Objection. 10 THE WITNESS: I never made 11 myself available as an expert 12 witness. I was contacted first by 13 Sidley Austin with respect to a 14 patent case. But they contacted 15 me. I didn't even know how that 16 came about. 17 BY MR. TISI: 18 Q. Okay. And when would that 19 have been? 20 A. You are stretching my memory 21 now. 2016. 22 Q. Have you ever told anybody 23 that you think it would be a good way to 24 make additional money to be a -- to be an</p>	<p style="text-align: right;">Page 153</p> <p>1 Page 48 and 49 of your report? 2 A. 48 and 49? 3 Q. Mm-hmm. I'm sorry. I must 4 have mistyped it. I apologize. Maybe 5 it's 38 and 39. 6 MS. MILLER: There's a table 7 of contents. 8 BY MR. TISI: 9 Q. Yeah, that may have it. On 10 Page 36. 11 A. Yes, I'm there. 12 Q. And that contains your 13 analysis of the non-epidemiologic 14 evidence, correct? 15 A. I don't think I would call 16 it non-epidemiologic evidence. I mean, 17 biological plausibility is part of the 18 Bradford Hill criteria. And that's what 19 epidemiologists use to -- 20 Q. Okay. Now, going back to 21 your conclusion, you say there was no 22 evidence of a causal relationship between 23 perineal and genital talcum powder 24 exposure and ovarian cancer, correct?</p>

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<p style="text-align: right;">Page 154</p> <p>1 A. That's what I state. 2 Q. And that's -- those are your 3 words? 4 A. Those are my words. 5 Q. And isn't it true that 6 outside of litigation -- now, this is a 7 litigation report. This was paid for by 8 Johnson & Johnson for the work that you 9 did, correct? 10 MS. MILLER: Objection. 11 There's two questions. 12 BY MR. TISI: 13 Q. The report -- the generation 14 of this report was paid for by Johnson & 15 Johnson? 16 MS. MILLER: Objection. 17 THE WITNESS: I did this 18 report as part of my expert 19 witness activities on the behalf 20 of Johnson & Johnson. 21 BY MR. TISI: 22 Q. For which you are paid? 23 A. For which I am paid. 24 Q. Okay. And isn't it true</p>	<p style="text-align: right;">Page 156</p> <p>1 BY MR. TISI: 2 Q. Well, I'm going to show you 3 one. Do you know who Dr. Narod is? 4 A. Not personally. 5 Q. Do you know him 6 professionally by reputation? 7 A. I know that I read an 8 article that he had published. 9 Q. Okay. And this article is 10 in Gynecologic Oncology. It's in your 11 report. 12 A. Yes. It's published in 13 Gynecologic Oncology. 14 Q. And it's an article entitled 15 "Talc and Ovarian Cancer"? 16 A. Yes. 17 Q. And it's an -- is this a 18 respected peer-reviewed journal? 19 A. I don't know what the impact 20 factor is of this journal. It is a 21 peer-reviewed journal. 22 Q. Does impact factor always 23 reflect the quality of the journal, the 24 actual academic quality of the journal?</p>
<p style="text-align: right;">Page 155</p> <p>1 that experts outside of litigation have 2 published the opinion that you expressed 3 here as disingenuous? 4 A. Can you show me? 5 Q. I'm going to. Have you 6 ever -- have you ever seen a description 7 of -- of that opinion as being 8 disingenuous? 9 MS. MILLER: Objection. 10 BY MR. TISI: 11 Q. In the published literature? 12 A. Not to my knowledge. Can I 13 see -- 14 Q. Sure. 15 A. -- what you're referring 16 to -- what you're referring to? 17 Q. Do you know of a -- do you 18 know of a publication by a Steven Narod, 19 M.D.? 20 A. Which publication? I'm sure 21 he has many. 22 (Document marked for 23 identification as Exhibit 24 Ballman-7.)</p>	<p style="text-align: right;">Page 157</p> <p>1 A. It depends upon who you talk 2 to. So journals that have high impact 3 factors tend to think it does. Probably 4 more than journals with low impact 5 factor. But in general, I think the 6 higher the impact factor there is a 7 correlation with the quality of the 8 journal. 9 Q. Have you published in 10 relatively low impact journals? 11 A. I have. 12 Q. So you don't have a 13 criticism of anybody who publishes in 14 a -- in a low impact journal, do you? 15 A. I don't know. That's a 16 broad question. 17 Q. Well we had some testimony 18 the other day from a witness who said, 19 "Well, only if it's a high impact" -- 20 paraphrasing, and I am paraphrasing, that 21 low impact journals are not as 22 significant as high impact journals in 23 terms of their scholarly -- scholarly 24 importance.</p>

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<p>1 MS. MILLER: Objection. 2 THE WITNESS: That's just 3 really broad. I mean, I think my 4 take on it is that high impact 5 journals have definitely probably 6 more of a rigorous peer review 7 process than do some lower impact 8 journals. But that -- that is not 9 an absolute. 10 BY MR. TISI: 11 Q. Because you publish -- 12 A. But I'm sure there's -- 13 Q. Because you publish in -- 14 A. -- exceptions. 15 Q. -- low impact journals, 16 right? 17 MS. MILLER: Objection. 18 Please stop interrupting 19 her. 20 BY MR. TISI: 21 Q. You publish in low impact 22 journals, correct? 23 A. I have. I don't -- I'm sure 24 there are some of the publications on my</p>	<p>1 exactly where you're reading? 2 Q. Sure. I'll show you mine. 3 A. Oh, there, thank you. Thank 4 you. 5 MS. SHARKO: Can I see it? 6 MR. TISI: You have it right 7 there. 8 MS. SHARKO: Thank you. 9 BY MR. TISI: 10 Q. It is unlikely that the 11 association between talc and ovarian 12 cancer is due to confounding, and so it 13 is fair to say that if there's a 14 statistically -- a statistically robust 15 relationship between talc and ovarian 16 cancer, it is likely to be causal, albeit 17 with intermediate factors, such as 18 inflammation. In any case, given the 19 number of hazard ratios in the literature 20 between 1.1 and 1.4 in both case-control 21 and cohort studies, it's disingenuous to 22 state there is no evidence that talc is 23 associated with ovarian cancer. 24 Do you see that?</p>
Page 159	Page 161
<p>1 list that are in lower impact journals 2 than others. 3 Q. Okay. Now, if I go to the 4 Narod article which is on your reference 5 list or on one of the lists. I forget 6 which one it is. 7 On the bottom of the 8 left-hand column, on the bottom, it 9 says -- I'm reading -- 10 MS. MILLER: What page are 11 you on? 12 BY MR. TISI: 13 Q. From about -- 14 MR. TISI: The second page. 15 BY MR. TISI: 16 Q. Left-hand column, about 17 60 percent of the way down. 18 Okay. It says the 19 following: And I'm going to read it, and 20 you tell me whether I read it correctly. 21 It is unlikely that the 22 association between talc and ovarian 23 cancer -- 24 A. Wait, wait. Can I find</p>	<p>1 A. I do see that. You did read 2 that correctly. 3 Q. Okay. I'm going to have 4 that statement of Dr. Narod -- 5 MS. MILLER: I was just 6 going to say you left one word out 7 in your reading -- 8 MS. SHARKO: I think he 9 says -- 10 THE WITNESS: Oh, you didn't 11 read that correct. 12 MR. TISI: I thought you 13 said you did read -- did I -- 14 THE WITNESS: I'm sorry. 15 BY MR. TISI: 16 Q. I'll read it again. Let me 17 put it in front of you. 18 (Document marked for 19 identification as Exhibit 20 Ballman-8.) 21 BY MR. TISI: 22 Q. This is Exhibit Number 8. 23 And I've highlighted -- 24 MS. MILLER: Again, this is</p>

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<p>1 called a conclusion but it comes 2 in the middle of the document. I 3 have -- 4 MR. LOCKE: This is 5 definitely -- I'm going to object. 6 This is definitely not the 7 conclusion. Read the last 8 paragraph. 9 MS. MILLER: I have an 10 objection to the mislabeling of so 11 far each of these exhibits. 12 MR. TISI: Let me tell you 13 what. I'm going to take out -- 14 you can block out the conclusion 15 if you want, if that will make you 16 happy, Counsel. 17 MS. MILLER: Thank you for 18 that offer. 19 MR. TISI: Okay. So you 20 won't do it. 21 BY MR. TISI: 22 Q. So, I'm -- Doctor, did I 23 read the statement correctly, that it is 24 unlikely that the association between</p>	<p>1 the -- the statement will be -- the 2 record will be -- 3 A. Yeah. 4 Q. -- from the article. 5 Do you see where it says, 6 "It's disingenuous to state that there is 7 no evidence that talc is associated with 8 ovarian cancer"? 9 A. Talc is -- 10 MR. TISI: Counsel, please. 11 MS. MILLER: I -- 12 THE WITNESS: "It is 13 disingenuous to state that there 14 is no evidence that talc is 15 associated with ovarian cancer." 16 BY MR. TISI: 17 Q. That's what he writes in his 18 non-litigation report, do you see it? 19 A. I -- I do see that. 20 Q. Okay. And you would 21 disagree with that statement, correct? 22 A. Well, I mean, it depends 23 upon how you parse things out. So you 24 know, it's disingenuous to state that</p>
Page 163	Page 165
<p>1 talc and ovarian cancer is due to 2 confounding, and so it is fair to say 3 that if there's a statistically robust 4 relationship between talc and ovarian 5 cancer is likely to be causal, albeit 6 with intermediate factors such as 7 inflammation. 8 Did I read that correctly? 9 MS. SHARKO: No, you didn't. 10 Is the word use missing here 11 too? He misread that. 12 MS. MILLER: That word "use" 13 is missing again. 14 MR. TISI: "Talc use and 15 ovarian cancer is likely to be 16 causal." 17 Did I not say that? 18 MS. MILLER: "Talc use". 19 BY MR. TISI: 20 Q. Do you see that statement? 21 A. Yeah, I see that statement. 22 And I'll take your word you read it 23 correctly. 24 Q. The statement will be what</p>	<p>1 there is no evidence that talc is 2 associated with ovarian cancer. So if 3 you mean that there are no studies that 4 have a statistically significant 5 association, that would be correct. 6 Q. Okay. 7 A. He is not stating there that 8 there is no evidence that talc is -- that 9 talc is -- that there's a causal 10 relationship between talc and ovarian 11 cancer. 12 Q. What -- he also says that 13 there -- that the association between 14 talc and ovarian cancer is unlikely due 15 to confounding, do you see that in the 16 first sentence? 17 A. Yes. 18 Q. And you disagree with that, 19 true? 20 A. Now, which sentence, can you 21 read -- 22 Q. The first sentence. "It is 23 unlikely that the association between 24 talc and ovarian cancer" --</p>

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<p style="text-align: right;">Page 166</p> <p>1 A. Oh, that one. 2 Q. -- "is due to confounding." 3 Do you disagree with that? 4 MR. LOCKE: Objection to the 5 term, "the first sentence." 6 THE WITNESS: Yeah. 7 MR. TISI: The first -- 8 okay. 9 THE WITNESS: It's of that 10 document. 11 BY MR. TISI: 12 Q. Correct. Of -- of exhibit 13 that -- 14 A. This one. 15 Q. Correct. 16 A. 8? 17 Q. Yes. 18 A. I -- I don't see any 19 references there's -- references to 20 support that statement. 21 Q. So you would disagree with 22 the statement? 23 A. Well, I -- I don't see any 24 references to support that.</p>	<p style="text-align: right;">Page 168</p> <p>1 his conclusion wrong? 2 A. I -- I would have to see the 3 references upon which he's making that 4 conclusion in order to assess that. 5 The data I looked at in 6 totality, I do see evidence of 7 confounding. In fact, we can go to the 8 Schildkraut study, and -- and there is a 9 pretty resounding evidence there that 10 there is recall bias, which is -- 11 Q. After 2014, correct? 12 A. Well, there's recall bias -- 13 no, there's recall bias even before that. 14 But it shows sort of how 15 much magnitude recall bias can have just 16 due to tweaking one little thing. 17 But I did not say that 18 there's no recall bias before 2014. 19 Q. So would you defer to the 20 authors of that study as to what the 21 meaning of that data meant? 22 A. No. Scientists don't do 23 that. Scientists look at publications. 24 They look at -- they looked at the</p>
<p style="text-align: right;">Page 167</p> <p>1 Q. So you disagree with the 2 statement? 3 MS. MILLER: Objection. 4 THE WITNESS: I'm just 5 saying I don't see any 6 references -- 7 BY MR. TISI: 8 Q. I understand. I'm not 9 asking you whether you see references. 10 I'm asking you whether you disagree with 11 the statement. 12 A. I believe in any sort of 13 observational study it is not possible to 14 conclude that there is no confounding. 15 Q. Okay. That's not what he 16 said, did he? 17 He said, "It is unlikely 18 that the association between talc and 19 ovarian cancer is due to confounding." 20 Do you see that? 21 A. I see he says unlikely. But 22 again, I -- there's -- there's no 23 references to support that. 24 Q. Okay. So my question is, is</p>	<p style="text-align: right;">Page 169</p> <p>1 methods. The methods of to be published. 2 They look at the analyses that were done 3 and the results that were done. And -- 4 and they evaluate whether or not they -- 5 they believe to the strength that the 6 authors do, that the authors' conclusions 7 are supported by all that. 8 Q. Now, Dr. Narod published his 9 opinions, correct? 10 A. Are these opinions? Yeah? 11 Q. Okay. I'm going to -- I'll 12 characterize them as opinion. Okay. 13 He published these 14 statements, correct? 15 A. Yes. This is statements 16 made in a paper that was published. 17 Q. Okay. And so he submitted 18 his -- his views to the scientific and 19 medical community, correct? 20 A. Yeah. I mean, the -- all 21 the views that's in this entire article, 22 I mean, so, you know, there's more words 23 than this than just the -- the two 24 sentences that were pulled out.</p>

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<p style="text-align: right;">Page 170</p> <p>1 Q. I agree, I agree. But he 2 submitted his -- his views to the 3 scientific and medical community for what 4 that's worth, correct? 5 A. This paper has been 6 published. 7 Q. Okay. The Health Canada 8 paper, even in its draft form, was put on 9 the internet. That's where you found it, 10 correct? 11 A. The Health Canada draft is 12 available for people to review. 13 Q. Okay. And comment on, which 14 you have not done, right? 15 A. I have not commented on the 16 Health Canada. 17 Q. Have you published your 18 opinions about talc? 19 A. I did research on this. And 20 I wrote an expert report. I have not 21 published my expert report. 22 Q. Have you submitted your 23 report to peer review? 24 A. That's sort of -- that would</p>	<p style="text-align: right;">Page 172</p> <p>1 Canada did, just like any of the other 2 authors of the studies that you've 3 reviewed, what your views on the level of 4 evidence there is for the general 5 causation question. 6 Are you -- do you intend to 7 publish? 8 MS. MILLER: Objection. 9 Again, that was two questions. 10 The first one was the 11 objectionable one. 12 THE WITNESS: So -- 13 MR. TISI: Let me rephrase 14 the question. 15 BY MR. TISI: 16 Q. Do you intend to publish on 17 the question about whether or not ovarian 18 cancer is caused by talcum powder 19 products? 20 A. I do not plan to publish. 21 Q. Now, in addition to offering 22 your own professional opinion on the 23 sufficiency of the evidence on talc and 24 ovarian cancer, I understand you may</p>
<p style="text-align: right;">Page 171</p> <p>1 be sort of odd. This -- this expert 2 report is written for a specific purpose. 3 If I'm going to do a peer-reviewed 4 article, it -- it would look a little 5 different from -- from this expert 6 report. 7 Q. So what specific purpose was 8 this article -- was this report written 9 for? 10 MS. MILLER: Objection. 11 THE WITNESS: So this report 12 was written to look at the 13 totality of the evidence that's 14 been published to determine 15 whether there is an association 16 between talc and ovarian cancer, a 17 causal relationship between talc 18 and ovarian cancer. 19 BY MR. TISI: 20 Q. Now, did you -- so would 21 you -- have you decided -- now that 22 you've done this review, are you going to 23 write a paper that would put out, just 24 like Dr. Narod did, just like Health</p>	<p style="text-align: right;">Page 173</p> <p>1 offer criticisms of plaintiffs' 2 epidemiology experts in this case; is 3 that true? 4 A. So, in my report, I point 5 out some -- I point out things that -- 6 other experts had said that -- that I 7 believe have limitations or that I don't 8 agree with. 9 Q. Well, for the record the 10 experts that you referred to in your 11 report are Jack Siemiatycki? 12 A. He's one expert. 13 Q. Do you know who Jack 14 Siemiatycki is? 15 A. I know who -- I know who he 16 is. But I've not met him. 17 Q. You understand that he's 18 well published in the field of cancer 19 epidemiology? 20 MS. MILLER: Objection. 21 THE WITNESS: I did not look 22 at his publication records. So I 23 don't know if he's well published 24 or not.</p>

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<p style="text-align: right;">Page 174</p> <p>1 BY MR. TISI: 2 Q. You know that he was the 3 chair of the IARC panel that dealt with 4 the issue of ovarian cancer and talc? 5 A. I believe when I read the 6 IARC -- I believe when I read his expert 7 report, that is what he stated. 8 Q. Do you have any reason to 9 believe that he's unqualified to offer 10 his opinions in this case on the general 11 question? Whether you disagree with his 12 conclusions, put that aside for a moment. 13 I'm asking you do you have 14 any qualms with his qualifications to 15 offer an opinion on the issue of general 16 causation? 17 MS. MILLER: Objection. 18 THE WITNESS: I don't think 19 it's my place to decide whether or 20 not someone has the qualifications 21 to offer an opinion. 22 BY MR. TISI: 23 Q. Well, we had a witness the 24 other day who said that he thought</p>	<p style="text-align: right;">Page 176</p> <p>1 epidemiologist and has -- I can't 2 remember if she's published in the area. 3 I presume she has. And, you know, one 4 can look at her publications. 5 Q. So I guess what I'm 6 hearing -- so let -- 7 THE VIDEOGRAPHER: Sorry. 8 You're covering your microphone. 9 BY MR. TISI: 10 Q. Let me summarize it. Do 11 you -- of any of plaintiffs' experts in 12 this case, do you intend to offer any 13 opinions that any of them are unqualified 14 to render an opinion on the general 15 causation question? 16 MS. MILLER: Objection. 17 THE WITNESS: I -- it's -- I 18 don't -- I was not asked to render 19 an opinion if I think that any of 20 the experts are unqualified or 21 not. And so I haven't seen 22 thought about that. 23 BY MR. TISI: 24 Q. And that's fine. Are all of</p>
<p style="text-align: right;">Page 175</p> <p>1 another one of plaintiffs' witnesses was 2 unqualified. I'm asking you, are you -- 3 do you think that this witness -- that 4 Dr. Siemiatycki is unqualified? 5 A. I believe he has -- he has 6 credentials in this area, and he's 7 done -- he was, as you said, the chair of 8 the IARC committee, and may even have 9 published in this area. 10 So, you know, when people 11 publish, yeah -- I don't know what the 12 word "qualified" means, but I think, you 13 know, he is a scientist. 14 Q. What about Anne McTiernan? 15 Do you have any qualms about her 16 qualifications to render an opinion on 17 the question of whether or not talc 18 causes ovarian cancer? 19 MS. MILLER: Objection. 20 THE WITNESS: I can't speak 21 to the qualifications. 22 BY MR. TISI: 23 Q. Okay. 24 A. I know that she's an</p>	<p style="text-align: right;">Page 177</p> <p>1 your opinions of these experts contained 2 in your expert report, Exhibit 1? 3 MS. MILLER: Objection. She 4 just said she has no opinions. 5 THE WITNESS: Are my 6 opinions of the actual experts? 7 BY MR. TISI: 8 Q. Yes. Of the actual experts, 9 of their conclusions, of their 10 methodology, are all of those opinions 11 contained in your expert report, Exhibit 12 Number 1? 13 MS. MILLER: Objection. I 14 don't understand that question. 15 MR. TISI: You don't have 16 to. As long as she understand it. 17 THE WITNESS: Yeah, I'm 18 confused too. 19 MS. MILLER: What? 20 THE WITNESS: Because I 21 thought I heard my opinions of the 22 experts -- 23 BY MR. TISI: 24 Q. I said --</p>

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<p>1 A. -- and I don't know why I 2 would have -- 3 Q. Are your criticisms of 4 your -- are all of the criticisms that 5 you have on plaintiffs' experts contained 6 in your expert report? 7 MS. MILLER: Her criticisms 8 of the experts' opinions? 9 MR. TISI: Yes. 10 MS. MILLER: Okay. That's 11 not what you said. 12 THE WITNESS: No, no, you 13 said experts. And so I'm still 14 confused. 15 BY MR. TISI: 16 Q. Okay. Are all of the 17 opinions related to plaintiffs' experts 18 contained in your expert report? 19 A. Are all my opinions related 20 to plaintiffs' experts? 21 Q. Mm-hmm. 22 A. Themselves? 23 Q. Mm-hmm. Of their opinions, 24 their methodology, any aspect --</p>	<p>1 number here. I disagree with that number 2 there, or I disagree -- so I guess I have 3 to say it's not complete. 4 Q. Okay. Are there any 5 opinions that you have as you sit here 6 today about any of the opinions that they 7 gave that are not in your report? 8 A. Without going through their 9 reports and going through my report to 10 make sure that every single criticism I 11 might have has been made, I can't answer 12 that with any sort of certainty. 13 Q. Okay. I'm going to have it 14 marked as Exhibit Number 9, your 15 curriculum vitae. 16 (Document marked for 17 identification as Exhibit 18 Ballman-9.) 19 BY MR. TISI: 20 Q. This is the one that was 21 provided with your expert report. Is 22 this your most recent curriculum vitae? 23 A. No. 24 Q. Is there one subsequent to</p>
Page 179	Page 181
<p>1 A. Okay. That's a little 2 different. Again, I heard, are my 3 opinions of the qualifications, or 4 whatever -- of the experts. 5 Q. I said -- I'm reading 6 verbatim. Are all of the opinions 7 related to plaintiffs' experts that you 8 have contained in your expert report? 9 A. See, that says are my 10 opinions of all the plaintiff experts. 11 To me, that's like my opinions on the 12 experts themselves, which I did not 13 address. 14 Q. Okay. I said related to the 15 expert. Okay. Let me -- let me rephrase 16 the question. 17 Are all of your criticisms 18 about the opinions that plaintiffs' 19 experts will offer in this case contained 20 in your report? 21 A. I mean, the ones I thought 22 were -- the most important are in here. 23 I can -- you know, I didn't go through 24 and say, okay, I disagree with this</p>	<p>1 that? 2 A. This says June 5th on it. 3 Q. Okay. Is the expert 4 report -- 5 MS. MILLER: She's looking. 6 THE WITNESS: The thing 7 that's attached as Exhibit A on my 8 expert report says February 22nd. 9 BY MR. TISI: 10 Q. Okay. So let's -- 11 A. So -- 12 Q. That's an old one. I have 13 it says February 22nd there. Am I wrong? 14 MS. MILLER: The one that 15 you gave us says June 5th. 16 MR. TISI: Okay. My office 17 must have printed it out wrong. 18 BY MR. TISI: 19 Q. Okay. So is Exhibit A to 20 your expert report your most recent 21 curriculum vitae? 22 A. It's the most -- 23 MS. MILLER: Shall we just 24 all refer back to Exhibit 1 for</p>

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<p style="text-align: right;">Page 182</p> <p>1 this portion of the questioning?</p> <p>2 MR. TISI: Yes, correct.</p> <p>3 Exhibit A.</p> <p>4 MS. MILLER: Of your</p> <p>5 Exhibit 1?</p> <p>6 MR. TISI: Exhibit 1.</p> <p>7 MS. MILLER: Exhibit A to</p> <p>8 Exhibit 1.</p> <p>9 MR. TISI: Correct.</p> <p>10 MS. MILLER: Just so we're</p> <p>11 all on the same page.</p> <p>12 MR. TISI: Thank you.</p> <p>13 THE WITNESS: It's the</p> <p>14 latest one that I updated.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Okay. Does this CV</p> <p>17 accurately summarize the experience that</p> <p>18 you believe qualifies you to render an</p> <p>19 epidemiologic opinion on the causation</p> <p>20 question in this case?</p> <p>21 A. That -- that's a broad</p> <p>22 question. I mean, I don't know if you</p> <p>23 can capture 20 years of -- of experience,</p> <p>24 you know, in one document, but it</p>	<p style="text-align: right;">Page 184</p> <p>1 correct?</p> <p>2 A. Not off the top of my head.</p> <p>3 Q. Okay. One more plaintiffs'</p> <p>4 epidemiology referred to in your expert</p> <p>5 report is April Zambelli-Wiener-Weiner.</p> <p>6 Do you remember? She looked at the</p> <p>7 Huncharek and Muscat publications in 2003</p> <p>8 and 2000 -- 2007, and then the 2011</p> <p>9 publication of the -- of their report to</p> <p>10 the FDA. Do you remember reading that?</p> <p>11 A. I remember reading her</p> <p>12 expert report. Can I -- can I see it? I</p> <p>13 don't remember if those were the actual</p> <p>14 studies that she -- I thought 2003 was --</p> <p>15 and I don't remember a 2011. So --</p> <p>16 Q. Okay. Let --</p> <p>17 A. -- but I did read her expert</p> <p>18 report.</p> <p>19 Q. Let's put aside 2011 for a</p> <p>20 moment. The diaphragm study, which was</p> <p>21 2007 and 2003 meta-analysis, you did read</p> <p>22 her report on those, correct?</p> <p>23 A. I read her expert report.</p> <p>24 Q. Okay. And you agree that</p>
<p style="text-align: right;">Page 183</p> <p>1 captures, you know, some highlights, yes.</p> <p>2 Q. Well, is there anything that</p> <p>3 you can think of in your experience,</p> <p>4 beyond what is in your expert report as</p> <p>5 you sit here right now, that would</p> <p>6 qualify you to testify on the issue of</p> <p>7 whether or not ovarian cancer is caused</p> <p>8 by talcum powder products?</p> <p>9 A. Well, in the -- in the</p> <p>10 addition to what is written here is my</p> <p>11 day in and day out daily activities</p> <p>12 when -- that I do as part of my job.</p> <p>13 That -- that has built up the experience</p> <p>14 over the years.</p> <p>15 Q. When is the last time -- do</p> <p>16 any of your publications anywhere refer</p> <p>17 to the Bradford Hill criteria?</p> <p>18 A. I have no idea. Nothing</p> <p>19 comes to the top of my head, but I can't</p> <p>20 say with certainty.</p> <p>21 Q. Okay.</p> <p>22 A. As you mentioned, there's</p> <p>23 like 200 some.</p> <p>24 Q. But none you can think of,</p>	<p style="text-align: right;">Page 185</p> <p>1 those reports contain -- those studies</p> <p>2 contain errors, correct?</p> <p>3 A. Yeah. Can I see her expert</p> <p>4 report, please?</p> <p>5 Q. I don't have it with me.</p> <p>6 Do you -- do you have any</p> <p>7 opinions as to whether -- did you look --</p> <p>8 when you were preparing your report, did</p> <p>9 you look at her report and try to confirm</p> <p>10 or not the errors that she identified</p> <p>11 with respect to those studies?</p> <p>12 MS. MILLER: Objection.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Was that part of what you</p> <p>15 were asked to do?</p> <p>16 MS. MILLER: Objection. I</p> <p>17 am sorry, objection after the</p> <p>18 first question. I didn't realize</p> <p>19 there would be two.</p> <p>20 THE WITNESS: So --</p> <p>21 BY MR. TISI:</p> <p>22 Q. Was it part of your -- in --</p> <p>23 in connection with preparing your expert</p> <p>24 report, did you look at whether or not</p>

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<p style="text-align: right;">Page 186</p> <p>1 there were substantive flaws in the</p> <p>2 analyses conducted by Drs. Huncharek and</p> <p>3 Muscat that Dr. Zambelli-Wiener-Weiner</p> <p>4 had identified?</p> <p>5 A. So you're asking me to</p> <p>6 remember, just off the top of my head</p> <p>7 what's in her report. I would very much</p> <p>8 like to see that report --</p> <p>9 Q. I'm asking you what you --</p> <p>10 I'm asking you what you did. Okay.</p> <p>11 Did you --</p> <p>12 A. I did look at her report and</p> <p>13 I did read through it.</p> <p>14 Q. Did you do any analysis of</p> <p>15 the Huncharek and Muscat articles?</p> <p>16 A. Oh, did I -- that's a</p> <p>17 different question. Did I do any</p> <p>18 analyses of their articles? I read</p> <p>19 through her report. I do remember that.</p> <p>20 I do remember her finding some error --</p> <p>21 or what she called errors, numbers that</p> <p>22 she couldn't match that they had reported</p> <p>23 in their report that came from other</p> <p>24 case-control studies and so forth.</p>	<p style="text-align: right;">Page 188</p> <p>1 of deposition --</p> <p>2 MS. MILLER: If you want</p> <p>3 Dr. Zambelli-Wiener-Weiner's</p> <p>4 report, we can have it brought in</p> <p>5 here.</p> <p>6 MR. TISI: I don't need to.</p> <p>7 BY MR. TISI:</p> <p>8 Q. This is the notice of</p> <p>9 deposition that we filed in this case.</p> <p>10 Have you seen that before?</p> <p>11 A. I have seen this document.</p> <p>12 Q. Okay. And you -- your</p> <p>13 counsel provided documents last night.</p> <p>14 And I'm not going to mark all of them.</p> <p>15 But because they will go out of order</p> <p>16 here, I'm going to mark them as 10, A, B,</p> <p>17 C, D, because they are in response to</p> <p>18 this notice of deposition.</p> <p>19 A supplemental list of</p> <p>20 materials, I'm going to have this marked</p> <p>21 as Exhibit Number 10A.</p> <p>22 (Document marked for</p> <p>23 identification as Exhibit</p> <p>24 Ballman-10.)</p>
<p style="text-align: right;">Page 187</p> <p>1 And I -- I remember her</p> <p>2 doing various different analyses that if</p> <p>3 they really used the studies that they</p> <p>4 claimed they used, what would the</p> <p>5 dose-response relationship, say, look</p> <p>6 like. And I remember it didn't matter,</p> <p>7 because there still was no dose-response</p> <p>8 relationship even when she did the</p> <p>9 analyses in the way she thought it should</p> <p>10 have been done.</p> <p>11 Q. So other than that, do you</p> <p>12 have any criticisms of her?</p> <p>13 A. I would have to go through</p> <p>14 my -- my report here and -- and see if</p> <p>15 I -- I actually sort of mention anything</p> <p>16 with respect to her actual report. I</p> <p>17 don't remember off of the top of my head.</p> <p>18 Q. Now, Exhibit Number 10 is</p> <p>19 the -- I'm going to ask --</p> <p>20 (Document marked for</p> <p>21 identification as Exhibit</p> <p>22 Ballman-10.)</p> <p>23 BY MR. TISI:</p> <p>24 Q. I'm going to mark the notice</p>	<p style="text-align: right;">Page 189</p> <p>1 (Document marked for</p> <p>2 identification as Exhibit</p> <p>3 Ballman-10-A.)</p> <p>4 BY MR. TISI:</p> <p>5 Q. And this one, Number 2, is</p> <p>6 the Health Canada document that we marked</p> <p>7 previously.</p> <p>8 A. It has it on it here, yes.</p> <p>9 Q. Okay.</p> <p>10 (Document marked for</p> <p>11 identification as Exhibit</p> <p>12 Ballman-10-B.)</p> <p>13 (Document marked for</p> <p>14 identification as Exhibit</p> <p>15 Ballman-10-C.)</p> <p>16 (Document marked for</p> <p>17 identification as Exhibit</p> <p>18 Ballman-10-D.)</p> <p>19 BY MR. TISI:</p> <p>20 Q. The next is an addendum to</p> <p>21 list of materials reviewed and considered</p> <p>22 by Karla Ballman. And I'm going to have</p> <p>23 this marked as Exhibit Number 10-B.</p> <p>24 10-C is your invoice dated</p>

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<p style="text-align: right;">Page 190</p> <p>1 3/7/2019, the one that Ms. Sharko has not 2 paid. 3 MS. MILLER: It's Skadden. 4 I think it's me who hasn't paid. 5 MR. TISI: Okay. 6 MS. MILLER: I'm the bad guy 7 here. 8 BY MR. TISI: 9 Q. Next one is an e-mail I'm 10 going to ask you in a moment about, from 11 Dr. Karla Ballman to Sandra Oquendo at 12 the FDA. 13 Can you tell me what that's 14 about? 15 MS. MILLER: Is that a 16 question now? 17 MR. TISI: Yes. 18 MS. MILLER: Are you done 19 marking them? 20 MR. TISI: No, I'm not done 21 marking them. I'm just going to 22 stop right there. 23 MS. MILLER: Oh, okay. 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 192</p> <p>1 exchange back and forth was to clarify 2 that you were? 3 MS. MILLER: Objection. 4 THE WITNESS: So can I see 5 the disclosure form? 6 BY MR. TISI: 7 Q. I don't -- I didn't print -- 8 it came too late last night for me to 9 print at the hotel. 10 But you -- 11 MS. MILLER: You printed the 12 e-mail but you didn't print the 13 disclosure it related to? 14 MR. TISI: Excuse me, 15 Counsel. I did not. 16 MS. MILLER: Okay. I -- 17 MR. TISI: Okay. If you 18 have a copy, you can feel free to 19 show it to her. 20 MS. MILLER: Can I get a 21 copy? 22 MR. TISI: But -- but -- 23 well, we'll go off the record and 24 you can get a copy.</p>
<p style="text-align: right;">Page 191</p> <p>1 Q. That's an e-mail that you 2 drafted on March 21, 2019, which would 3 have been -- I don't know what today's 4 date is. That may have been yesterday. 5 A. Yeah, I've been getting my 6 dates mixed up this week. 7 Q. This is an e-mail disclosing 8 to the FDA that you are an expert for 9 Johnson & Johnson in the talc litigation? 10 A. So the first e-mail I -- is 11 sending an updated disclosure form to the 12 FDA. 13 Q. Right. 14 A. The second e-mail is a 15 response from them asking for 16 clarification or answers to some specific 17 questions. 18 And then the last e-mail is 19 my saying here are my responses. 20 Q. Okay. But -- but is it fair 21 to say that you initially provided a 22 disclosure form to -- for the FDA that 23 did not disclose you were an expert for 24 Johnson & Johnson and that this e-mail</p>	<p style="text-align: right;">Page 193</p> <p>1 MS. MILLER: Okay. Let's go 2 off the record and I'll get a 3 copy. 4 THE VIDEOGRAPHER: Remove 5 your microphones. The time is 6 11:33 a.m. Off the record. 7 (Short break.) 8 THE VIDEOGRAPHER: Okay. We 9 are back on the record. The time 10 is 11:48 a.m. 11 BY MR. TISI: 12 Q. Doctor, we took a quick 13 break so that you could look at some 14 documents. Could you tell us why you 15 amended your FDA form yesterday to 16 indicate that you had done some 17 consulting on the talc litigation with 18 J&J? 19 A. So this is for an FDA panel 20 and they wanted a disclosure. And so the 21 first time that I submitted my disclosure 22 I believe it was January 23rd. I listed 23 Johnson & Johnson and \$12,000. So I 24 looked at the box, it says, "Expert</p>

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<p style="text-align: right;">Page 194</p> <p>1 witness, last 12 months." I saw last 2 12 months. "I appeared for or against 3 the following listed firms/issues." 4 And then I saw amount 5 received. 6 So when I saw that, I was 7 like okay, what they want is in the last 8 12 months any money I got from -- that I 9 actually physically got in the last 10 12 months from doing expert work. And so 11 this was the amount that I had received 12 in the last 12 months. 13 So as part of the, what is 14 this notice called? As part of 15 document -- Exhibit 10, the request was 16 for all disclosures made to the FDA, so I 17 was looking through and trying to find 18 all disclosures. And I -- I am learning 19 through my experience here that I need to 20 understand and look at words much more 21 carefully. And so I re-read this again. 22 And then I saw -- and I am 23 sure I read it the first time. But it 24 just didn't register to me. It says "or</p>	<p style="text-align: right;">Page 196</p> <p>1 ongoing work that I'm doing, Johnson & 2 Johnson talc powder litigation -- that's 3 the issue -- and the amount that I 4 billed. 5 Q. And now I notice that these 6 do not contain -- it's supposed to go 7 back 12 months? 8 A. Yes. 9 Q. They did not contain the 10 Viagra work that you've done? 11 A. There was another 12 confidential document that accompanied 13 this, that I believe the decision was 14 made -- I don't know what the legal terms 15 are. And there was a list of all the 16 companies that they wanted just that 17 information on, if I had any sort of 18 engagement with the companies on that 19 list. 20 Q. Who is they? The FDA? 21 A. The FDA. There was another 22 document that accompanied this that 23 explains sort of, you know, the 24 confidentiality disclosure. It says</p>
<p style="text-align: right;">Page 195</p> <p>1 under negotiation." 2 And so I started thinking 3 about that, and I thought, well, you 4 know, they probably don't really mean 5 just under negotiation, that probably 6 encompasses ongoing work. 7 So I felt it was prudent to 8 amend my disclosure to the FDA to let 9 them know about the ongoing work for 10 which I had not received any money in the 11 last 12 months. And that is the document 12 that is -- is dated incorrectly. I sent 13 the document on the 20th. 3/21/2019. I 14 had my dates mixed up. 15 In there I went through and 16 another thing I had missed is it said 17 firm/issue. So I -- I thought, well, I 18 better also put the issue -- I -- I 19 missed that too the first time. 20 So you now see it says, 21 "Johnson & Johnson/Zytiga patent 22 (prostate cancer)," the amount received. 23 That did not change. 24 And then I added this</p>	<p style="text-align: right;">Page 197</p> <p>1 confidential on top. And that's why it 2 wasn't shared. 3 And Johnson & Johnson was 4 the only firm that I've done any work 5 with that was on that list. 6 Q. Okay. And so you didn't 7 feel that you needed to indicate that you 8 were an expert witness for the 9 manufacturers in Viagra/Cialis, based 10 upon Number F -- Letter F on this form, 11 that says, "Expert witness last 12 months 12 or negotiation, I appeared for or against 13 the following firms/issues." 14 MR. LOCKE: Objection to 15 form. 16 THE WITNESS: Yes, 17 because -- 18 BY MR. TISI: 19 Q. It doesn't -- it doesn't 20 limit to it on the attached list. It 21 simply says -- 22 A. No, but in the confidential 23 document that wasn't, it said, "Please 24 disclose any" -- "Please disclose for the</p>

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<p style="text-align: right;">Page 198</p> <p>1 firms listed on this list." 2 MS. MILLER: There's a cover 3 memo. I can explain. There's a 4 cover memo. And it said do not 5 disclose. Because it said do not 6 disclose and it wasn't the actual 7 conflicts, we did not produce it. 8 BY MR. TISI: 9 Q. Okay. But can we agree the 10 form doesn't -- the form itself -- the 11 disclosure form doesn't limit -- I mean, 12 I can't test this -- your -- because I 13 can't see the document. 14 But what I'm asking you is, 15 the form itself that's filed doesn't list 16 Viagra/Cialis litigation, does it? 17 A. I mean, as you see on the 18 form there, it is not listed, because 19 again, in the cover letter that went with 20 this, the confidential cover letter that 21 says, "Please disclose any engagement 22 with these specific companies," Lilly was 23 not on that. 24 Q. Okay. Let me ask you -- I'm</p>	<p style="text-align: right;">Page 200</p> <p>1 is a different -- two different things, 2 correct? 3 A. Now I'm confused. I mean -- 4 Q. Okay. Let me -- because I 5 don't want to get -- I don't want to get 6 bogged down. 7 Would you agree with me that 8 these three -- these courses that you 9 taught deal primarily with trial design, 10 statistical methods or biostatistics 11 review? 12 MS. MILLER: Objection. 13 BY MR. TISI: 14 Q. We can argue about whether 15 it's epidemiology or not later. Would 16 you agree that that is the focus? 17 MS. MILLER: Objection. 18 Really try to stick to one 19 question. I'm really pleading 20 with you. 21 MR. TISI: She's looking at 22 me like I've lost my mind. 23 THE WITNESS: Well, no, 24 because, I mean -- I mean -- I</p>
<p style="text-align: right;">Page 199</p> <p>1 going to mark this as 10-E. 2 (Document marked for 3 identification as Exhibit 4 Ballman-10-E.) 5 BY MR. TISI: 6 Q. This is the lectures and 7 workshops on epidemiology. And you wrote 8 epidemiology biostatistics. Is it fair 9 to say that all of these -- all of these 10 have to do with trial designs, 11 statistical methods, or biostatistics? 12 A. So you would say that 13 meta-analyses is not epidemiology? You 14 would say trial design is most 15 epidemiology? I think most 16 epidemiologists would disagree with that. 17 Q. I'm asking you -- there's a 18 difference between trial design and trial 19 analysis and causation analysis, is there 20 not? 21 MS. MILLER: Objection. 22 BY MR. TISI: 23 Q. I mean, doing a study and 24 doing a review of the medical literature</p>	<p style="text-align: right;">Page 201</p> <p>1 mean, clinical trials is 2 epidemiology. It's study design. 3 Biomarker development, that had 4 epidemiology in it because it's 5 very dependent upon study design 6 and what you can say and what you 7 can't say. 8 The trial -- the value of 9 trials, we were talking about 10 meta-analyses. So that -- that, 11 that lecture involved 12 meta-analyses and what a 13 meta-analysis is so forth. As you 14 see in most -- you know, this 15 litigation involves many 16 meta-analyses, and we're calling 17 it epidemiology. 18 BY MR. TISI: 19 Q. I didn't ask you whether -- 20 I simply asked you -- and, you know, 21 forgive me if I think you're being 22 defensive here. 23 MS. MILLER: Objection. 24 BY MR. TISI:</p>

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<p>1 Q. Okay. Okay. Because I've 2 simply asked are these primarily focused 3 on trial design, statistical methods, and 4 biostatistics review. 5 MS. MILLER: Objection. 6 THE WITNESS: I don't know 7 how to answer that because, I 8 mean, that's what the titles say. 9 BY MR. TISI: 10 Q. Thank you. 11 A. But it does not say sort of 12 what the content is of -- 13 Q. I'm going to ask you that 14 question. You really need to -- you 15 really need to answer my question, and 16 then I will ask the follow-up questions. 17 So are these -- the next 18 question that I'm going to ask, do any of 19 these in any of these courses or 20 lectures, did you teach students how to 21 do a Bradford Hill analysis? 22 MS. MILLER: Objection. Is 23 this about courses? I thought it 24 was just lectures.</p>	<p>1 A. Just, just a very vague. 2 Q. What is your understanding? 3 MS. MILLER: Objection. 4 That's a legal question. I don't 5 think that's a question for an 6 expert. That's a question for a 7 lawyer. 8 BY MR. TISI: 9 Q. What is your -- 10 MR. TISI: I understand. 11 BY MR. TISI: 12 Q. What is your understanding? 13 MS. MILLER: She's not an 14 expert on the law -- 15 MR. TISI: I'm asking her 16 what her understanding is. 17 THE WITNESS: I -- 18 MS. MILLER: I understand, 19 but I don't think that's an 20 appropriate question. 21 MR. TISI: Okay. Fine. 22 THE WITNESS: Yeah, I don't 23 even know if I -- I even want to 24 hazard what my understanding is,</p>
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<p>1 MR. TISI: Lectures. In any 2 of these lectures. 3 MS. MILLER: You said 4 courses. 5 THE WITNESS: I don't 6 believe Bradford Hill was 7 mentioned in -- in these 8 particular lectures, no. 9 BY MR. TISI: 10 Q. Okay. Okay. Now before we 11 discuss any further, let me just go back 12 and -- and ask you. 13 The front page of your 14 report talks about general causation 15 Daubert hearings, the page that you 16 signed, correct, on Exhibit 1? 17 A. That's what it says. 18 Q. Okay. And has -- has it 19 been explained to you or do you have any 20 understanding -- let me rephrase the 21 question. 22 Do you have any 23 understanding as to what Daubert hearings 24 are?</p>	<p>1 because that's outside the scope 2 of my expertise. 3 And I -- I've been learning, 4 as I have mentioned, I've been 5 learning through these processes 6 that the words I use are very 7 important. And so I am just not 8 even going to hazard. 9 BY MR. TISI: 10 Q. Whether you -- do you know 11 whether or not in these hearings the 12 question is going to be whether or not 13 the witnesses are qualified? 14 MS. MILLER: Objection. 15 BY MR. TISI: 16 Q. Do you have any 17 understanding of that? 18 MS. MILLER: Objection. 19 Again, that was two questions. I 20 think it's really hard when you 21 ask two questions. I'm sorry to 22 keep repeating this. 23 BY MR. TISI: 24 Q. Do you have -- do you have</p>

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<p>1 any understanding as to one in the issues 2 in the Daubert hearings is whether the 3 witness is qualified to give an opinion 4 on which they are proffered to give an 5 opinion on? 6 A. I -- I -- my understanding 7 is, is experts should be experts in -- in 8 the area that they were retained for. 9 Q. And use a proper 10 methodology, correct? 11 A. Well, if they were experts, 12 I would presume that -- that they use -- 13 they are experts in their area so they 14 know what to do. 15 Q. Do you have any -- 16 MS. MILLER: Objection. 17 BY MR. TISI: 18 Q. And that -- so, you agree 19 with me that being qualified experts in 20 the field, that the plaintiffs' experts 21 as your -- have used a proper 22 methodology, they all looked at Bradford 23 Hill, correct? 24 MS. MILLER: Objection.</p>	<p>1 THE WITNESS: I mean, 2 that -- that's a very vague 3 question. So I -- I can say what 4 I did. I looked at the totality 5 of the evidence using established 6 epidemiology framework, and I came 7 to the conclusion that there is no 8 credible evidence -- 9 BY MR. TISI: 10 Q. Okay. 11 A. -- of a causal association 12 between talc and -- 13 Q. I understand that you -- 14 MR. TISI: Again, she's not 15 answering my question -- 16 MS. MILLER: She still has 17 to -- 18 MR. TISI: No, I understand, 19 but she can't filibuster. 20 BY MR. TISI: 21 Q. I'm -- I didn't ask you what 22 you did. 23 I'm asking you, did the 24 experts when you read their reports on</p>
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<p>1 THE WITNESS: Yeah, that's 2 starting to go beyond my -- my 3 understanding of law. I mean I 4 know that the -- both sides have 5 experts and they -- both sides' 6 experts say what they're experts 7 in, are -- were retained on the 8 basis of what their expertise is, 9 but that -- that's basically all I 10 know. 11 BY MR. TISI: 12 Q. Do you have any reason to 13 believe, based upon -- you may disagree 14 with some of the weights or -- and I 15 think you're pretty clear in your report 16 of some of the criticisms that you have 17 about the way in which certain evidence 18 was looked at by some plaintiffs' 19 experts. Putting aside Smith-Bindman's 20 meta-analysis for a moment. 21 Isn't it fair to say that 22 they applied the same general methodology 23 that you did? 24 MS. MILLER: Objection.</p>	<p>1 the plaintiffs' side, whether you agreed 2 or disagreed with their conclusions, did 3 they use the same framework that you did? 4 MS. MILLER: Objection. 5 THE WITNESS: I -- I can't 6 say that. 7 BY MR. TISI: 8 Q. Okay. 9 A. I mean, I -- I don't know -- 10 Q. And that's fine then. Just 11 answer it that way. 12 A. Okay. I -- I can't say that 13 with certainty. 14 Q. That's fine. 15 Is there any methodologic 16 flaw, apart from you that you gave 17 different -- different weights to the 18 evidence and you looked at the evidence 19 differently, is there any methodologic 20 flaw that you have identified in any of 21 the plaintiffs' experts' reports? 22 MS. MILLER: Objection. Is 23 there a specific expert you're 24 referring to?</p>

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<p>1 MR. TISI: I'm -- if she 2 says yes, I will then go through 3 them. 4 BY MR. TISI: 5 Q. Apart from Smith-Bindman. 6 And I know you have a whole section on 7 Smith-Bindman. 8 A. Well, I -- I also have sort 9 of -- I -- I address other opinions that 10 experts have made and -- and say why I -- 11 I don't believe that the scientific 12 evidence supports what they -- they came 13 to. 14 So obviously, I mean that -- 15 that's -- that I think is part and parcel 16 as to -- 17 Q. But that's a conclusion 18 question, right? So -- so -- 19 MS. SHARKO: You can't 20 interrupt the witness. 21 MR. TISI: You know, she -- 22 MS. MILLER: This is crazy. 23 MR. TISI: All right. You 24 know --</p>	<p>1 I assume your learned 2 counsel here knows how to defend a 3 deposition. Can I assume that? 4 MS. SHARKO: Are we going to 5 take my deposition now? 6 MR. TISI: Well, I mean, 7 unless -- if you want to go under 8 oath I'm happy to ask you 9 questions. 10 MS. SHARKO: Is that a -- 11 MR. TISI: Otherwise -- 12 otherwise, I would appreciate it 13 if you would simply observe. 14 BY MR. TISI: 15 Q. So, Dr. Ballman, have you 16 identified any methodologic -- apart from 17 disagreeing about some of the weights 18 that Dr. Siemiatycki ascribed to certain 19 studies, do you have any criticism of the 20 methodology he used? 21 A. Of what he used in his 22 meta-analyses? 23 Q. In hi -- in any -- in his 24 report, entirely.</p>
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<p>1 MS. MILLER: You've 2 interrupted every sentence that 3 she's given you since we came back 4 from the break and that's just not 5 fair. 6 MR. TISI: I must tell you, 7 you are not going to do this. 8 MS. MILLER: I'm not going 9 to do what? 10 MR. TISI: So -- so -- let 11 me -- let me -- 12 MS. SHARKO: You're not 13 going to do this. 14 MR. TISI: Are we doing one 15 or two now? 16 MS. SHARKO: Mr. Tisi, you 17 can't interrupt the witness. 18 MR. TISI: Okay. 19 MS. SHARKO: You know that, 20 so behave yourself. 21 MR. TISI: We have -- so why 22 don't you switch seats -- you can 23 switch seats and we can go -- 24 we -- we can have one at a time.</p>	<p>1 A. So, I mean, overall, you 2 know, I -- I think that there are flaws 3 in the methodology of all the experts. 4 Q. Okay. Tell me what -- tell 5 me what they are. 6 A. Well, we can go through my 7 report. 8 Q. No, I want you -- you can go 9 through your report. But I -- just give 10 me a general understanding about what 11 your criticism with Dr. Siemiatycki is. 12 MS. MILLER: If you need to 13 look at your report -- 14 THE WITNESS: Yeah, I 15 can't -- 16 MS. MILLER: -- don't let 17 him prevent you from looking at 18 your report. 19 THE WITNESS: Yeah, and I 20 need to -- I need to look at 21 his -- the expert report of 22 Dr. Siemiatycki in order to make 23 sure that -- 24 BY MR. TISI:</p>

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<p style="text-align: right;">Page 214</p> <p>1 Q. As you sit here right now 2 without looking at his report, do you 3 have any criticisms of Dr. Siemiatycki 4 that you can -- that you can articulate 5 for me? 6 MS. MILLER: Objection. 7 That's not fair. The witness said 8 she needs to look at her report. 9 She needs to look at his report. 10 This is not a memory test, is it? 11 MR. TISI: I'm here to take 12 her deposition. 13 BY MR. TISI: 14 Q. So I'd like to know, as you 15 sit here -- I assume you spent time with 16 counsel preparing, correct? 17 A. I would like to see the 18 reports, please, because I don't want to 19 misstate something just because my memory 20 is -- is not well -- doing well right 21 now. 22 Q. So you cannot -- you 23 cannot -- is it fair to say that you 24 cannot offer an opinion as to the</p>	<p style="text-align: right;">Page 216</p> <p>1 so I don't know exactly what I'm going to 2 be questioned on. 3 Q. Okay. Now, you offered an 4 opinion in the Viagra Cialis product 5 liability litigation? 6 A. I did. 7 Q. Like in this case, you were 8 asked by a pharmaceutical company lawyer 9 to testify on issues about whether or not 10 a product causes a disease, correct? 11 MR. LOCKE: Objection. 12 THE WITNESS: In Viagra, I 13 was asked to evaluate the totality 14 of the evidence that exists as to 15 whether or not exposure to Cialis, 16 in particular, I think, because 17 Lilly, I think, is Cialis and not 18 Viagra. 19 Whether or not it causes 20 melanoma. 21 BY MR. TISI: 22 Q. Okay. So the answer to my 23 question is you were asked to look at a 24 general causation question as to whether</p>
<p style="text-align: right;">Page 215</p> <p>1 methodologic flaws of Jack Siemiatycki 2 without sitting here and going through 3 his report? 4 MS. MILLER: Objection. 5 BY MR. TISI: 6 Q. Because I assumed you would 7 have done that before today. 8 MS. MILLER: Objection. 9 THE WITNESS: I think it's 10 fair to say that I have reviewed 11 many expert reports. I wrote my 12 report. And everything is 13 becoming a jumble. And I just 14 want to make sure that I -- I can 15 refresh my memory in order to 16 render the opinions you're looking 17 for. 18 BY MR. TISI: 19 Q. Do you understand that in a 20 Daubert hearing that you too will be 21 questioned about your -- both your 22 qualifications and your methodology? Do 23 you understand that? 24 A. I -- I -- I'm not a lawyer,</p>	<p style="text-align: right;">Page 217</p> <p>1 or not a product causes a disease? 2 MS. MILLER: Objection. 3 THE WITNESS: I don't 4 know -- 5 MS. MILLER: Please. 6 THE WITNESS: -- that the -- 7 I'm sorry. 8 Can I answer? 9 BY MR. TISI: 10 Q. Please. 11 MS. MILLER: Of course. 12 Just give me time. That's all I'm 13 asking. 14 THE WITNESS: So, I don't 15 know what general causation means. 16 BY MR. TISI: 17 Q. I didn't ask you general 18 causation. 19 A. I thought you did. 20 Q. If I did -- the question was 21 to whether -- 22 MS. MILLER: "So the answer 23 to my question is you were asked 24 to look at a general causation</p>

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<p style="text-align: right;">Page 218</p> <p>1 question." You did say --</p> <p>2 MR. TISI: Well, I wasn't</p> <p>3 talking general causation.</p> <p>4 BY MR. TISI:</p> <p>5 Q. A general question about</p> <p>6 whether or not a product causes a</p> <p>7 disease.</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: Again, I told</p> <p>10 you what I was asked to look for</p> <p>11 there. I was -- and I am giving</p> <p>12 specifics rather than</p> <p>13 generalities. I was asked to look</p> <p>14 at the totality of the</p> <p>15 epidemiology literature as to</p> <p>16 whether or not there is evidence</p> <p>17 that use of Cialis or a PDE5</p> <p>18 inhibitor more generally causes</p> <p>19 melanoma.</p> <p>20 BY MR. TISI:</p> <p>21 Q. Okay. And so you were</p> <p>22 looking about a causation question?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: Again, I told</p>	<p style="text-align: right;">Page 220</p> <p>1 That was your deposition.</p> <p>2 A. Oh, okay. Okay.</p> <p>3 Q. Okay. Your --</p> <p>4 A. Yeah, the report was</p> <p>5 probably midyear.</p> <p>6 Q. Was the causation --</p> <p>7 causation methodology that you employed</p> <p>8 to look at the question about whether or</p> <p>9 not Cialis was capable of causing</p> <p>10 melanoma the same methodology you used in</p> <p>11 this case?</p> <p>12 A. My general approach was</p> <p>13 similar. I review the data. I -- or the</p> <p>14 literature. I -- I, you know, determine,</p> <p>15 you know, whether or not there appears to</p> <p>16 be evidence of causation using</p> <p>17 established epidemiology principles and I</p> <p>18 come to a conclusion.</p> <p>19 Q. Is there any -- did you</p> <p>20 change your methodology at all between</p> <p>21 Viagra/Cialis and this case. In other</p> <p>22 words, did you use a different -- a</p> <p>23 different standard to evaluate evidence</p> <p>24 or the same standard?</p>
<p style="text-align: right;">Page 219</p> <p>1 you what I was -- I don't know</p> <p>2 why --</p> <p>3 BY MR. TISI:</p> <p>4 Q. You can't tell me whether or</p> <p>5 not you were looking at a causation</p> <p>6 question in Viagra/Cialis?</p> <p>7 A. I think I answered that. I</p> <p>8 want to be very specific at what I looked</p> <p>9 at.</p> <p>10 Q. And I'm being very -- and</p> <p>11 I'm trying to ask you a question.</p> <p>12 Let me ask you. Let me</p> <p>13 change it.</p> <p>14 Did your talc general</p> <p>15 causation report lay out your</p> <p>16 qualifications -- let me rephrase the</p> <p>17 question.</p> <p>18 Your Viagra/Cialis report</p> <p>19 was issued last year in mid-2018,</p> <p>20 correct?</p> <p>21 A. I believe that's about</p> <p>22 the -- or October maybe. I'm not -- I</p> <p>23 don't know.</p> <p>24 Q. That was your deposition.</p>	<p style="text-align: right;">Page 221</p> <p>1 MS. MILLER: Objection.</p> <p>2 BY MR. TISI:</p> <p>3 Q. In that case as you did</p> <p>4 here?</p> <p>5 MS. MILLER: Sorry. I</p> <p>6 thought you were done. Objection.</p> <p>7 THE WITNESS: I don't know</p> <p>8 what you mean different standard</p> <p>9 versus the same standard.</p> <p>10 Are you talking about did I</p> <p>11 use different words in my report?</p> <p>12 Did I use different --</p> <p>13 BY MR. TISI:</p> <p>14 Q. No. I'm asking whether you</p> <p>15 used the same general framework. For</p> <p>16 example, did you use the Bradford Hill</p> <p>17 framework with respect to Viagra Cialis</p> <p>18 that you used here?</p> <p>19 A. I used established</p> <p>20 epidemiology principles for looking at</p> <p>21 causation, which are based in the</p> <p>22 Bradford Hill criteria.</p> <p>23 Q. Okay. And is there anything</p> <p>24 that you can think of that would be</p>

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<p style="text-align: right;">Page 222</p> <p>1 different -- in other words, if I looked 2 at your Viagra Cialis deposition and your 3 expert report, would it reflect the same 4 methodology that you used here? 5 A. I -- I don't know how you 6 would -- 7 Q. Putting aside the evidence. 8 MS. MILLER: She was in the 9 middle of -- 10 MR. TISI: Well, I -- I -- 11 MS. MILLER: She was 12 literally in the middle of the 13 sentence. I don't think -- 14 MR. TISI: I am going to 15 withdraw the question, Counsel. 16 MS. MILLER: Okay. 17 BY MR. TISI: 18 Q. Okay. Putting aside the 19 fact that the evidence is different -- I 20 mean, obviously it's a different product, 21 different disease here. Putting that 22 issue aside. 23 If the same -- did you apply 24 the same general framework and approach</p>	<p style="text-align: right;">Page 224</p> <p>1 BY MR. TISI: 2 Q. Okay. And is there any 3 difference that you can think of in the 4 approach that you made in Viagra-Cialis 5 than you did here? 6 A. I -- I'm not sure what 7 you're looking for. I have my -- 8 Q. I'm not looking for 9 anything. I'm just looking to say, if 10 you were giving a lecture to -- to 11 students and say, you know, in both of 12 these I use the same -- you know, this is 13 how you do it. For example, in 14 Viagra-Cialis I did it the same way I did 15 it in the talc litigation. 16 MS. MILLER: Objection. 17 BY MR. TISI: 18 Q. Did you do it the same? 19 A. Again, I said I reviewed the 20 literature, I applied Bradford Hill 21 criteria as the basis as to determining 22 whether or not there is causality, and I 23 rendered an opinion. 24 Q. Was the description of the</p>
<p style="text-align: right;">Page 223</p> <p>1 in looking at the causation question in 2 Viagra/Cialis as you did here? 3 MS. MILLER: Same 4 objections. 5 THE WITNESS: So, as I 6 explained, I -- I -- and I don't 7 know how to explain it any 8 differently. 9 So I -- I looked at all the 10 available evidence that was in the 11 literature. I used the Bradford 12 Hill criteria as the basis for 13 looking at whether or not there 14 was causation, and then I -- I 15 rendered sort of what I -- what my 16 opinion was. 17 BY MR. TISI: 18 Q. And that is the -- that is 19 the standard epidemiologic methodology, 20 true? 21 MS. MILLER: Objection. 22 THE WITNESS: I think it's 23 an accepted epidemiological -- or 24 epidemiologic methodology.</p>	<p style="text-align: right;">Page 225</p> <p>1 methodology you used in Viagra-Cialis 2 truthful? 3 MS. MILLER: Objection. Do 4 you want to put in front of her -- 5 MR. TISI: No, I don't. 6 MS. MILLER: But that's not 7 fair. 8 MR. TISI: I asked her -- 9 MS. MILLER: You are turning 10 this deposition into a memory 11 test. 12 MR. TISI: Counsel. 13 Counsel, this is not a memory 14 test. 15 MS. MILLER: Okay. 16 BY MR. TISI: 17 Q. Did you -- is there 18 anything -- have you re-read your 19 deposition in Viagra-Cialis? 20 A. My deposition? 21 Q. Mm-hmm. 22 A. No. 23 Q. Do you know that there's -- 24 A. Well, the deposition?</p>

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<p>1 Q. Mm-hmm. 2 A. In Viagra-Cialis? 3 Q. Mm-hmm. 4 A. I've read parts of it, yes. 5 Q. Okay. Do you know that 6 there's a Daubert challenge to you in 7 Viagra-Cialis? 8 A. Yes, I am aware of that. 9 Q. Okay. And you know that the 10 hearing is in June, correct? 11 A. No, I didn't know that. 12 Q. Okay. Have you not been 13 told that there's a hearing set? 14 A. No, I have not been told 15 that. 16 Q. And is there anything about 17 your approach in Viagra-Cialis as a 18 result of re-reading your testimony that 19 you would change about your approach that 20 you did it here? 21 A. No. 22 MS. MILLER: Objection. 23 BY MR. TISI: 24 Q. Okay. So that --</p>	<p>1 MS. MILLER: Okay. Go 2 ahead. 3 BY MR. TISI: 4 Q. Would you agree that -- 5 you've testified to this before, sort of 6 about epidemiology and biostatistics. 7 While there's some overlap obviously 8 between biostatistics and epidemiology, 9 you've pointed that out. And these are 10 related fields, that they are two 11 distinct scientific disciplines? 12 A. I think, as I mentioned, 13 that at the basic level, the overlap is 14 almost complete between epidemiology and 15 biostatistics. 16 Q. Okay. 17 A. So Epi 101 and Biostats 101 18 are -- are very, very similar. If you 19 would look at table of contents of books 20 they would have similar concepts being -- 21 being taught. 22 I would also say that within 23 clinical research the overlap between 24 epidemiology and biostatistics is very</p>
Page 227	Page 229
<p>1 MS. MILLER: Please try to 2 remember to leave me time to 3 object, please. 4 BY MR. TISI: 5 Q. Would you -- 6 MS. MILLER: You two are 7 talking over each other and I'm 8 not having an opportunity to 9 object properly. 10 I want the record to show my 11 objection before your answer. 12 MR. TISI: How about if I 13 just agree that you object to 14 every question and we can move on? 15 MS. MILLER: How about we 16 just agree that you start asking 17 unobjectionable questions? It 18 would be so much smoother -- 19 MR. TISI: I am so happy -- 20 MS. MILLER: -- and the depo 21 would go so much quicker. 22 MR. TISI: -- I will submit 23 every question I have to the 24 court.</p>	<p>1 complete. 2 I would also say that 3 epidemiology as a field has other areas 4 that aren't so overlapped with 5 biostatistics, such as public health. 6 That -- that is a pure epi sort of topic. 7 Within biostats, there are 8 areas in biostats that are not that 9 overlapping with epidemiology. It's the 10 area where people want to develop new 11 mathematical techniques and so that's 12 almost more overlapping with mathematics 13 because of the theory beneath it. 14 And so I, as a clinical 15 research in my career over the last 16 20-some years, sits right in that really 17 overlapped area. And so that's what -- 18 what I do. 19 Q. Okay. Let me -- let me move 20 to strike the answer because it wasn't -- 21 that wasn't my question. 22 My question was, would you 23 agree -- let me -- me give you a 24 different question.</p>

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<p>1 Would you agree that being 2 an epidemiologist does not automatically 3 qualify a professional as a statistician 4 or biostatistician? 5 MS. MILLER: Objection. 6 THE WITNESS: I -- I'm not 7 sure what exactly you're -- you're 8 asking there. 9 BY MR. TISI: 10 Q. Has every -- can every 11 epidemiologist do what you do? 12 A. I -- I would have to see 13 what the particular epidemiologist -- 14 Q. I'm not asking that -- 15 A. -- the experience and 16 training is in order to -- 17 Q. Because -- because they are 18 distinct fields, true? 19 There is overlap, just like 20 cardiology and cardiac surgery, overlap, 21 right? 22 MS. MILLER: Objection. 23 She's -- 24 BY MR. TISI:</p>	<p>1 MS. MILLER: Objection. 2 What do you mean by her website? 3 MR. TISI: Can we have the 4 next exhibit, please. Exhibit 11. 5 (Document marked for 6 identification as Exhibit 7 Ballman-11.) 8 BY MR. TISI: 9 Q. This is your website from 10 Weill Cornell? 11 A. I -- I don't know if it's my 12 website. I believe it's the division's 13 website of biostatistics and 14 epidemiology. 15 Q. It has your picture on it? 16 A. Well, it has my picture on 17 it, but it says biostatistics and 18 epidemiology. It doesn't say Karla 19 Ballman at the top. 20 Q. Actually it says, "Weill 21 Cornell Medical Center Biostatistics and 22 Epidemiology," correct? 23 A. Way at the top, yes. 24 Q. Right. And underneath your</p>
Page 231	Page 233
<p>1 Q. Epidemiology and 2 biostatistics overlap, true? 3 MS. MILLER: That's three 4 questions. I'm looking at the -- 5 BY MR. TISI: 6 Q. I'm asking you the question: 7 Do epidemiology and biostatistics 8 overlap? 9 A. They overlap considerably in 10 some areas. 11 Medicine and epidemiology 12 overlap. There are medical doctors that 13 do epidemiology. But medicine is very 14 different and distinct discipline from 15 epidemiology. 16 Q. Is epidemiology concerned 17 with the distribution causation and 18 control of disease across time and space 19 and human populations? 20 A. I believe that's one 21 definition that one could use. 22 Q. In fact, that's the 23 definition on your website, is it not? 24 A. It may well be.</p>	<p>1 picture it says Dr. Karla Ballman? 2 A. Yes, that's correct. 3 Q. And underneath that it has 4 two separate definitions, one for 5 biostatistics and one for epidemiology, 6 correct? 7 A. Yeah, that's what's there. 8 Q. "Epidemiology says it's 9 concerned with the distribution, 10 causation, and control of disease across 11 time and space in human population." 12 Do you see that? 13 A. Yes, that's what's written 14 there, yes. 15 Q. Okay. And underneath -- 16 above that is a section that says, 17 "Biostatistics is the application of 18 statistical techniques to scientific 19 research in health-related fields 20 including medicine, biology, and public 21 health in the development of novel 22 methodologies that could improve the 23 application. Since the beginning of the 24 Twentieth Century, the field of</p>

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<p>1 biostatistics has become an in 2 dispensable tool in improving health and 3 reducing illness." 4 Correct? 5 A. What you read there is what 6 it states. I mean, I'll point out that's 7 this is a biostatistics -- 8 Q. That's all I asked. 9 A. -- and epidemiology 10 department -- 11 Q. All I asked is whether I 12 read it correctly. 13 A. You did read it correctly. 14 Q. Thank you. This is your 15 website for your department, correct? 16 A. So I don't think you're 17 letting me sort of address what you're 18 trying to imply. 19 Q. I'm not trying to imply 20 anything. 21 MS. MILLER: Please, let her 22 answer. 23 MR. TISI: No, the problem 24 is -- I think her answer really</p>	<p>1 definitions, one for biostatistics and 2 one for epidemiology, correct? 3 MS. MILLER: Objection. 4 THE WITNESS: It has -- it 5 has two statements there. One for 6 biostatistics and one for 7 epidemiology. And then it has, 8 "The mission of the division of 9 biostatistics and epidemiology." 10 And that's not -- that's the 11 mission of our division -- 12 MR. TISI: Counsel -- 13 THE WITNESS: -- which is to 14 develop epidemiologic studies in 15 the fields of hypertension, 16 women's health, perioperative -- 17 MR. TISI: -- honestly can 18 you just ask your witness to 19 answer the question. 20 THE WITNESS: -- outcomes and 21 anesthesiology. And that is 22 actually quite outdated because we 23 do more than that. 24 MR. TISI: Okay. Okay.</p>
Page 235	Page 237
<p>1 illustrates the problems here. 2 She's anticipating where she 3 thinks that I'm going. I'm asking 4 her very straightforward 5 questions. 6 BY MR. TISI: 7 Q. The question is, is this 8 your department's web page? 9 A. Yes. 10 MS. MILLER: I think you 11 know the answer to that. So 12 that's -- 13 MR. TISI: Okay. Well, I 14 have to put it on the record, 15 Counsel. 16 BY MR. TISI: 17 Q. Is it your department's web 18 page? 19 A. I believe it is. I haven't 20 been out at that web page in -- I don't 21 know when. So if you say this is what 22 you got from our -- as our division's web 23 page, I will take that as your word. 24 Q. And it has two separate</p>	<p>1 Counsel, I'm really going to ask 2 you, maybe we can take a break and 3 you can ask your witness to answer 4 the question. 5 BY MR. TISI: 6 Q. I'm simply asking, are there 7 two separate definitions on this page? 8 MS. MILLER: You've asked 9 that three times. 10 MR. TISI: Well, but I'm not 11 getting an answer. She wants to 12 go and read the rest of the 13 document. 14 MS. MILLER: You said it 15 has -- she did answer. "It has 16 two separate definitions" -- 17 MR. TISI: And she goes on. 18 MS. MILLER: -- "one for 19 biostatistics and one for 20 epidemiology, correct?" And she 21 says, "It has two statements 22 there, one for biostatistics and 23 one for epidemiology. And then it 24 has the mission of division of</p>

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<p>1 biostatistics" -- 2 MR. TISI: Did I ask her 3 that? Did I ask her about the 4 mission? 5 MS. MILLER: Did she not 6 answer your question, sir? 7 MR. TISI: Yes, but then she 8 goes on a speech. 9 MS. MILLER: You are pulling 10 statements out of context -- 11 MR. TISI: I'm not pulling 12 it out of context. 13 MS. MILLER: -- and she's 14 providing some context. She's 15 providing the context -- 16 MR. TISI: Counsel. 17 Counsel. 18 MS. MILLER: Why are you 19 yelling at me? 20 MR. TISI: Because I think 21 this is bizarre. 22 MS. MILLER: Really? I 23 think you're -- 24 MR. TISI: I simply asked</p>	<p>1 Q. These are two separate -- 2 these are two separate statements by 3 biostatistics and epidemiology, true? 4 MS. MILLER: Objection. 5 Asked and answered four times or 6 five. 7 BY MR. TISI: 8 Q. Are they separate 9 statements? 10 A. They are separate 11 statements. 12 Q. Thank you. 13 A. Because -- 14 MS. MILLER: Finish your 15 sentence if you'd like to. 16 THE WITNESS: Well, they are 17 separate statements, because it 18 says biostatistics and 19 epidemiology on top. So, I mean, 20 why wouldn't you have sort of two 21 separate, you know -- 22 BY MR. TISI: 23 Q. I am not asking why you 24 would. I'm just asking whether you do.</p>
Page 239	Page 241
<p>1 are there two definitions on the 2 page, one for epidemiology. I did 3 not ask anything about the mission 4 of the department, did I? 5 MS. MILLER: She answered 6 your question. 7 THE WITNESS: Actually, can 8 I -- can I. You said two 9 definitions. And I said -- I 10 think I said two statements. It 11 nowhere here says these are 12 definitions. 13 BY MR. TISI: 14 Q. Okay. 15 A. These are just descriptions, 16 and it's not a definition. And -- okay. 17 Q. I'll let -- I'll let -- I'll 18 let the judge and jury decide whether or 19 not these are definitions when it says 20 "biostatistics is" and "epidemiology is." 21 We'll let them decide that. 22 MS. MILLER: What jury are 23 you talking about? 24 BY MR. TISI:</p>	<p>1 A. Yeah, there are two 2 separate -- 3 Q. Perfect. 4 A. -- descriptions. 5 Q. Perfect. Now, the next 6 question is, there are people within your 7 department who actually do have degrees 8 in epidemiology, true? 9 A. I know of one. Can you name 10 several more? 11 Q. Dr. Drusin. He's a medical 12 doctor with a degree in epidemiology? 13 A. He is adjunct -- he is in my 14 department -- my division I think. But 15 it's unclear as to whether he belongs 16 there, because we had a whole -- had a 17 whole restructure of our department a 18 while ago. And there were other 19 divisions, and he belonged to a different 20 division and got put into my -- 21 Q. Does Dr. Gerber have a Ph.D. 22 in epidemiology? 23 A. She does have a Ph.D. in 24 epidemiology and does -- and we talked</p>

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<p>1 about her work --</p> <p>2 Q. I just asked you whether she</p> <p>3 had it. That's all. Simple question.</p> <p>4 A. Okay. I'm just trying to</p> <p>5 say that she feels she's more of a</p> <p>6 biostatistician.</p> <p>7 Q. I'm not asking what she</p> <p>8 feels, Doctor. I really am asking you,</p> <p>9 does she have a degree in epidemiology.</p> <p>10 A. She has a degree in</p> <p>11 epidemiology.</p> <p>12 Q. Does Dr. -- does Professor</p> <p>13 Christos have a master's in epidemiology?</p> <p>14 A. I don't know. I believe</p> <p>15 it's in public health.</p> <p>16 Q. Okay.</p> <p>17 A. Which is different from</p> <p>18 epidemiology --</p> <p>19 Q. Now --</p> <p>20 A. -- in the same way as</p> <p>21 statistics -- a lot of overlap, like with</p> <p>22 biostatistics.</p> <p>23 Q. Doctor, I'm going to show</p> <p>24 you what's marked as Exhibit Number 12.</p>	<p>1 A. You read that correctly.</p> <p>2 Q. Would you please go to the</p> <p>3 next page and look down the page, and</p> <p>4 when you were asked that question, what</p> <p>5 did you say?</p> <p>6 A. So -- and I believe I</p> <p>7 answered this before.</p> <p>8 Q. I'm just asking what you</p> <p>9 said. Would you read into the record</p> <p>10 what you said.</p> <p>11 A. I will. I will.</p> <p>12 Q. Thank you.</p> <p>13 A. And again, I'm just</p> <p>14 reiterating that this is --</p> <p>15 Q. You don't need to reiterate.</p> <p>16 I'm just simply asking you what you said.</p> <p>17 A. So it says, "I'm Karla</p> <p>18 Ballman. I'm the division chief of</p> <p>19 biostatistics and epidemiology at Weill</p> <p>20 Cornell Medicine in New York City, and</p> <p>21 obviously I'm a statistician."</p> <p>22 Q. Thank you.</p> <p>23 A. Let me point out that there</p> <p>24 are others here who also have MPH</p>
Page 243	Page 245
<p>1 This will be very quick.</p> <p>2 (Document marked for</p> <p>3 identification as Exhibit</p> <p>4 Ballman-12.)</p> <p>5 BY MR. TISI:</p> <p>6 Q. This is a portion of a</p> <p>7 transcript from the Center For Devices</p> <p>8 and Radiologic Health Medical Advisory</p> <p>9 Committee that you sat on in June of</p> <p>10 2018.</p> <p>11 Do you see that?</p> <p>12 A. Well, I -- I see the</p> <p>13 document that you handed me, yes.</p> <p>14 Q. And in the -- on Page 7 it</p> <p>15 says, from Dr. Nathan, it says -- fourth</p> <p>16 paragraph down, "Before we begin, I'd</p> <p>17 like to ask our distinguished panel</p> <p>18 members and FDA staff seated at this</p> <p>19 table to introduce themselves. Please</p> <p>20 state your name, your area of expertise,</p> <p>21 your position, and your affiliation.</p> <p>22 We'll go counterclockwise and start with</p> <p>23 Ms. Barnes."</p> <p>24 Do you see that?</p>	<p>1 degrees, and they identify themselves as</p> <p>2 doctors.</p> <p>3 So again it depends upon</p> <p>4 what role you play within these</p> <p>5 committees.</p> <p>6 Q. Doctor, you are a member of</p> <p>7 SARC, what is SARC?</p> <p>8 A. SARC is the -- is a</p> <p>9 nonprofit organization that does research</p> <p>10 in sarcoma.</p> <p>11 Q. Okay. And there's a web</p> <p>12 page for you on SARC.</p> <p>13 (Document marked for</p> <p>14 identification as Exhibit</p> <p>15 Ballman-13.)</p> <p>16 BY MR. TISI:</p> <p>17 Q. Exhibit Number 13.</p> <p>18 Does it identify you as</p> <p>19 statistician at the top?</p> <p>20 A. It does say statistician at</p> <p>21 the top. But it says I'm professor of</p> <p>22 biostatistics in the division of Weill</p> <p>23 Cornell biostatistics and epidemiology.</p> <p>24 "She is a recognized expert in cancer</p>

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<p style="text-align: right;">Page 246</p> <p>1 research study design and analyses for 2 clinical trials." 3 There's that overlap again 4 with epidemiology. 5 Q. Does it say anything about 6 causation there? 7 MS. MILLER: Objection. 8 BY MR. TISI: 9 Q. To say I'm an expert in 10 analyzing whether or not substances cause 11 disease? 12 MS. MILLER: Objection. 13 THE WITNESS: That -- that's 14 very specific. 15 Let me say that if you -- 16 BY MR. TISI: 17 Q. Does it say that there? 18 MS. MILLER: Objection. 19 THE WITNESS: Well, it 20 doesn't say that there, but -- 21 BY MR. TISI: 22 Q. Thank you. 23 A. -- it doesn't say many 24 things that -- that I do.</p>	<p style="text-align: right;">Page 248</p> <p>1 Q. This is the website of the 2 American Statistical Association. And it 3 says the -- it says, "The American 4 Statistical Association is the world's 5 largest community of statisticians. The 6 Big 10 for statistics." 7 Do you see that? 8 A. Yeah. I -- I just don't 9 know. This is -- I -- I don't know where 10 you pulled this off from the ASA. So I 11 mean, that's what it says on this 12 particular page. 13 Q. And it has a directory, if 14 you go to the last page, and you are 15 listed as a consultant. 16 Do you see that? 17 A. Yes, I see that. 18 Q. It has your phone number and 19 your e-mail address and all the 20 information? 21 A. Yeah, mm-hmm. 22 Q. Okay. Could you read -- 23 read for the record what you identified 24 to your colleagues as your areas of</p>
<p style="text-align: right;">Page 247</p> <p>1 Q. Are you a member of the -- 2 what's known as the American Statistical 3 Association? 4 A. I am. 5 Q. What is the American 6 Statistical Association? 7 A. It's the American 8 Statistical Association. 9 Q. Is it a reputable 10 organization of statisticians? 11 MS. MILLER: Objection. 12 THE WITNESS: And 13 epidemiologists. 14 BY MR. TISI: 15 Q. Okay. And -- and 16 epidemiologists. Okay. 17 And the American Statistical 18 organization, is -- and I'm going to have 19 this marked as exhibit -- what is this, 20 Exhibit 14? 21 (Document marked for 22 identification as Exhibit 23 Ballman-14.) 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 249</p> <p>1 expertise? 2 A. Biometrics, and 3 biostatistics, and -- and data collection 4 procedures, operations research, and 5 statistical training. 6 Q. Anything else? 7 A. Well, I just want to point 8 out that again data collection procedures 9 is -- is an area of epidemiology, and 10 biometrics and biostatistics, as I said, 11 also have considerable overlap with 12 epidemiology. 13 Q. By the way, the American -- 14 you were an officer in the American 15 Statistical Association, I think you 16 said? 17 A. Did I say that? 18 Q. I think it's in your -- I 19 think it's in your CV, your CV. 20 A. I'll have to look at my CV. 21 But I -- I did play some roles in there 22 at some point. 23 Q. They were volunteer roles, 24 right?</p>

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<p>1 A. They were volunteer roles. 2 Q. Have you ever -- do you know 3 what it takes to be a fellow at the 4 American Statistical Association? 5 A. No, I do not. 6 Q. Okay. Do you know that they 7 have a fellow program where colleagues 8 have -- can nominate people with 9 distinguished careers in statistics for 10 membership in their organization? 11 A. I -- 12 MS. MILLER: She just said 13 she doesn't know what it is. 14 MR. TISI: Then let's mark 15 it. 16 THE WITNESS: Well, I -- I 17 don't know the specifics of it. 18 But I -- I believe that's the 19 purpose of -- and most fellowships 20 in any profession have that. 21 (Document marked for 22 identification as Exhibit 23 Ballman-15.) 24 BY MR. TISI:</p>	<p>1 three-page exhibit. But the first 2 two pages are Page 1 of 2 and the 3 last one is Page 2 of 2. 4 Do you want me to pull out 5 this so that it's an accurate 6 exhibit? 7 MR. TISI: That's fine. 8 Thank you. 9 MS. MILLER: So here we go. 10 I've pulled out the middle page, 11 and now we have Page 1 of 2 and 12 Page 2 of 2. 13 BY MR. TISI: 14 Q. Okay. Have you ever been 15 nominated as an ASA fellow, do you know? 16 A. I have no idea. 17 Q. Okay. Have you -- are -- 18 you are not an ASA fellow, are you? 19 A. I am not an ASA fellow. 20 Q. Okay. And to be clear, an 21 ASA fellow would be somebody whose 22 contribution to the advancement of 23 statistical science and places due weight 24 on public works, positions held with</p>
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<p>1 Q. I'm going to -- yeah. 2 Other than my -- and I -- I 3 sent this to my e-mail address, and I 4 apologize. 5 But other than that, this is 6 a list from the website from the ASA. 7 A. Mm-hmm. 8 MR. TISI: I only have one 9 copy I printed out this morning, 10 I'm sorry, Counsel, if you would 11 share it. 12 BY MR. TISI: 13 Q. It says, "A designation of 14 an ASA fellow has been a significant 15 honor for nearly 100 years. People 16 can" -- 17 MS. MILLER: Actually isn't 18 every page the same? 19 THE WITNESS: Oh yeah. 20 MR. TISI: Maybe it is. I 21 apologize. 22 MS. MILLER: Wait, this is 23 confusing. I just want to state 24 for the record that this is a</p>	<p>1 employer, ASA activities, membership and 2 accomplishments in societies, and 3 professional activities. 4 And you are not -- you 5 have -- you are not a fellow, correct? 6 MS. MILLER: Objection. 7 THE WITNESS: I am not. 8 MS. MILLER: Please. 9 THE WITNESS: You read that 10 correctly. I am not a fellow. 11 BY MR. TISI: 12 Q. In applying for funds -- 13 actually let me stop for a second. 14 You know, from time to time 15 the ASA issues statements about 16 statistical issues? 17 A. I'm vaguely aware that they 18 issue statements from time to time. 19 Q. Okay. In your CV you 20 identify past or present current grants. 21 Have you -- do you know if whether you 22 have ever asked for a -- identified 23 yourself as an epidemiologist by title, 24 as an epidemiologist, not as part of your</p>

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<p>1 department?</p> <p>2 MS. MILLER: Objection.</p> <p>3 BY MR. TISI:</p> <p>4 Q. As you are describing</p> <p>5 yourself, in a -- in a grant that you</p> <p>6 have ever given for any purpose?</p> <p>7 MS. MILLER: You just kicked</p> <p>8 me. Objection.</p> <p>9 MR. TISI: I apologize.</p> <p>10 THE WITNESS: I -- I have</p> <p>11 been on so many grant and grant</p> <p>12 applications that I cannot off the</p> <p>13 top of my head tell you whether or</p> <p>14 not I have ever said I am an</p> <p>15 epidemiologist.</p> <p>16 BY MR. TISI:</p> <p>17 Q. Have you ever to your</p> <p>18 knowledge ever stood up in a public</p> <p>19 meeting and said, "I, Karla Ballman, is</p> <p>20 an -- I am an epidemiologist"?</p> <p>21 MS. MILLER: Objection.</p> <p>22 BY MR. TISI:</p> <p>23 Q. Like you did before, and</p> <p>24 say, "I'm a statistician"?</p>	<p>1 A. I have been to many</p> <p>2 professional and public meetings, I don't</p> <p>3 know if I've ever stood up and said with</p> <p>4 certainty -- I cannot answer if I've ever</p> <p>5 stood up and said that.</p> <p>6 I do have to say that when</p> <p>7 people hear biostatistics and clinical</p> <p>8 research, they intertwine epidemiology</p> <p>9 and biostatistics, so --</p> <p>10 Q. But you have never</p> <p>11 represented to your colleagues</p> <p>12 affirmatively, "I, Karla Ballman, an</p> <p>13 epidemiologist"?</p> <p>14 MS. MILLER: Objection.</p> <p>15 THE WITNESS: Again, in</p> <p>16 situations and studies I'm in, by</p> <p>17 saying a biostatistics and knowing</p> <p>18 that I do cancer research, they</p> <p>19 know what that means and they know</p> <p>20 it involves study design. As you</p> <p>21 can look in my CV, I have many</p> <p>22 case-control -- I've done</p> <p>23 case-control studies. I've done</p> <p>24 cohort studies. I've done --</p>
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<p>1 MS. MILLER: Objection.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Have you ever told your</p> <p>4 colleagues, "I am an epidemiologist"?</p> <p>5 MS. MILLER: It's really</p> <p>6 hard, because I don't know when</p> <p>7 your question ends. Because you</p> <p>8 ask a question, and then I object,</p> <p>9 and then you keep going.</p> <p>10 MR. TISI: Okay. Fine. I'm</p> <p>11 sorry.</p> <p>12 MS. MILLER: It's a very</p> <p>13 complicated --</p> <p>14 MR. TISI: I'm sorry it's</p> <p>15 hard.</p> <p>16 MS. MILLER: -- record. But</p> <p>17 it's not fair to the witness,</p> <p>18 because I don't -- do you know</p> <p>19 what question --</p> <p>20 THE WITNESS: I'll --</p> <p>21 BY MR. TISI:</p> <p>22 Q. Have you ever stood up in a</p> <p>23 public professional meeting and said, "I,</p> <p>24 Karla Ballman, an epidemiologist"?</p>	<p>1 BY MR. TISI:</p> <p>2 Q. Okay. Your department, your</p> <p>3 department offers a two-month review</p> <p>4 course in epidemiology, taught by</p> <p>5 Dr. Christos. Do you know that? In</p> <p>6 October/November of every year?</p> <p>7 A. Is it called a review</p> <p>8 course?</p> <p>9 Q. Yes.</p> <p>10 A. I'm just having some -- and</p> <p>11 can I see where you are getting at and</p> <p>12 what it is?</p> <p>13 Q. Exhibit 16.</p> <p>14 A. I just want to see what</p> <p>15 program it's a part of. I'm not</p> <p>16 disputing that.</p> <p>17 (Document marked for</p> <p>18 identification as Exhibit</p> <p>19 Ballman-16.)</p> <p>20 THE WITNESS: Is it part of</p> <p>21 the CTSC program?</p> <p>22 MR. TISI: Honestly, I've</p> <p>23 got to -- I thought it was here.</p> <p>24 BY MR. TISI:</p>

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<p>1 Q. This is Exhibit Number 17, 2 which is the list of courses that I got 3 from the Weill Cornell website. 4 A. I see, okay. 5 Q. Do you see where I'm 6 referring to? 7 A. Are you -- go ahead. Ask 8 your question. I'll let you say it. 9 MS. MILLER: This is 17. 10 Catherine saying she says that she 11 doesn't believe there's a 16, that 12 you went from 15 to 17. Is that 13 correct? 14 MR. SOILEAU: He referenced 15 a 16, but then essentially 16 withdrew it and moved to a new 17 document and marked it as 17. 18 MR. TISI: So why don't we 19 mark it as 16. 20 MS. MILLER: Why don't we 21 mark it 16 for clarity going 22 forward. Thank you, Catherine. 23 BY MR. TISI: 24 Q. So to be clear, this is the</p>	<p>1 Q. I'm asking with -- the title 2 of the course. I'm not asking the 3 content now. So you made that very 4 clear, that it overlaps, and the record 5 is clear on that. 6 I'm asking you have you ever 7 taught a course with the word 8 "epidemiology" in it? 9 A. I do not believe I've taught 10 a course with epidemiology in it. Most 11 of those courses would be intro courses, 12 and when I teach intro courses, I come at 13 it and teach it from the biostats side. 14 That includes epidemiology as a part of 15 it. But I have not taught an 16 epidemiology 101 course. No, I've not 17 had a course with epidemiology in the 18 title. 19 Q. In fact -- in fact, the only 20 two courses that you taught at Cornell 21 Weill are introduction to biostatistics 22 and biostatistics 1? 23 A. I'm trying to remember the 24 titles. And, again, I don't know where</p>
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<p>1 list of courses that are offered by the 2 Weill Cornell Medical Center in 3 biostatistics and epidemiology? 4 A. I don't know. Because Madhu 5 Mazumdar who is listed there, that was 6 the individual I replaced. So I don't 7 know where -- I mean, his is not 8 reflective of anything we're -- 9 Q. You see the date on top is 10 three -- March 2019. I mean, it's off 11 the website. I don't know what to tell 12 you, other than that's where I got it. 13 A. Yeah, I agree. I don't know 14 what to tell you either. But that just 15 shows you that we don't keep our website 16 up to date. But Madhu Mazumdar has not 17 been at Weill Cornell for almost four 18 years, if not more than four years so. 19 Q. Let me ask you this. Have 20 you ever taught a course with the word 21 "epidemiology" in it? 22 MS. MILLER: Objection. In 23 the course or in the course -- 24 BY MR. TISI:</p>	<p>1 you're getting that information from. So 2 I want to make sure the titles are 3 correct. 4 MS. MILLER: Is that in your 5 CV? 6 MR. TISI: It is. 7 THE WITNESS: Okay. If it's 8 in my CV. Thank you. And if -- I 9 have only taught two courses. I 10 am not quibbling about that. 11 BY MR. TISI: 12 Q. Thank you. 13 A. I'm just trying to see, you 14 know, if it says intro to biostats or -- 15 okay. Yeah one is part of the executive 16 MBA/MS program. And the other is part of 17 our biostatistics and data science 18 program. Those are two courses that I 19 have taught at Weill Cornell. 20 Q. Does Weill Cornell offer a 21 Ph.D. or an MPH in epidemiology? 22 A. Weill Cornell itself? 23 Q. Mm-hmm. 24 A. No, it does not.</p>

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<p>1 Q. Does -- and Cornell only 2 offers epidemiology as a minor, correct? 3 A. I -- I couldn't comment on 4 that. I don't know what the main campus 5 offers. 6 MS. MILLER: Were you asking 7 Cornell, as in not Weill Cornell 8 but undergraduate? You said -- as 9 in undergraduate courses? 10 MR. TISI: I said in 11 Cornell, regular Cornell, the 12 Cornell upstate in Ithaca. 13 BY MR. TISI: 14 Q. To be clear, you have no 15 publications on ovarian cancer, correct? 16 MS. MILLER: Objection. 17 Asked and answered. 18 THE WITNESS: I have no 19 publications that have -- I 20 believe, that are on ovarian 21 cancer. 22 BY MR. TISI: 23 Q. Any publications on the risk 24 factors for ovarian cancer?</p>	<p>1 A. But the -- 2 Q. But let's let -- 3 MS. MILLER: That's not what 4 he said. 5 THE WITNESS: He didn't say 6 the methodology differed. 7 MR. TISI: Let's -- let's 8 move on. 9 THE WITNESS: He said the 10 individual risk factors differed 11 is my understanding. 12 MS. MILLER: She said in 13 terms of how one would evaluate 14 factors. You're mischaracterizing 15 her testimony. 16 BY MR. TISI: 17 Q. Are there any publications 18 on your CV related to talc? 19 A. No, there are not. 20 Q. Any publications even 21 mention talc and cancer in the same 22 article? 23 MS. MILLER: Objection. 24 We've been through this.</p>
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<p>1 MS. MILLER: Objection. 2 THE WITNESS: Again, I just 3 said I have no publications in 4 ovarian cancer. I have 5 publications on -- that evaluate 6 risk factors for many other 7 cancers. 8 BY MR. TISI: 9 Q. But not ovarian? 10 A. Not ovarian, per se, but 11 ovarian cancer is not any different from 12 other cancers in terms of how one would 13 evaluate risk factors. 14 Q. That's not what Dr. Neel 15 told us the other day. So we'll have to 16 see whether he's right or you're right. 17 A. Can you show me that 18 statement? I believe he was talking 19 about that there's issues about different 20 subtypes of ovarian cancer. I didn't see 21 that -- and that -- I don't think he said 22 that -- 23 Q. He was very clear that risk 24 factors are different between the two.</p>	<p>1 THE WITNESS: I cannot say 2 that with certainty. 3 I -- you know, it's 4 definitely not in the title, but I 5 can't say for sure if -- if there 6 was talc somewhere mentioned in 7 all 200 publications. I don't 8 know with certainty. 9 BY MR. TISI: 10 Q. Any publications about 11 asbestos? 12 A. No. 13 Q. Any publications about 14 asbestos and ovarian cancer? 15 A. Again, there are no 16 publications in ovarian cancer. So no. 17 Q. Any publications where you 18 reviewed evidence regarding causation for 19 any disease through a Bradford Hill 20 guideline? 21 A. So that is a little harder 22 to -- to -- I'll have to go through and 23 look through all the things. I mean, 24 I -- I don't know for certain whether or</p>

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<p style="text-align: right;">Page 266</p> <p>1 not I discuss -- any of the publications 2 discuss causation. 3 I know I have publications 4 that establish associations with things. 5 And we just don't go any further, because 6 association is not causation and there 7 was no reason to establish whether it was 8 causal or not. 9 Q. Right. So my question is, 10 have you ever done an article where you 11 did what you did here, which is look at 12 all the evidence, try to synthesize it 13 and determine whether or not there's 14 cause and effect that you can think of? 15 MS. MILLER: Objection. 16 THE WITNESS: So I would 17 have to say that I believe there 18 are articles here that we have 19 established association and we 20 realize that it -- it didn't merit 21 going through Bradford Hill 22 because it was -- because of the 23 methodology we did, that, you 24 know, we weren't -- we didn't</p>	<p style="text-align: right;">Page 268</p> <p>1 in publication, in some of my 2 publications, as I used in this analysis. 3 Q. Do you think that if I went 4 through each and every article there 5 would be any mention of Bradford Hill? 6 A. I'm not sure with 7 100 percent certainty. But that may well 8 be the case. Just again, because it 9 doesn't say Bradford Hill does not mean 10 that the underlying methodology that was 11 used was not based on the Bradford Hill 12 framework. 13 Q. Isn't it true that your 14 contribution to the vast majority of your 15 200-plus articles is statistical design 16 and statistical evaluation and to the 17 statistical methods you used in the paper 18 and that you are not either the first 19 author or the last author? 20 MS. MILLER: Objection. 21 That's like very, very, very 22 compound. 23 THE WITNESS: I don't quite 24 understand the question. I mean,</p>
<p style="text-align: right;">Page 267</p> <p>1 think there -- it was sufficient 2 to, like perhaps the odds -- the 3 risk ratio was like 1.3 or 4 something, pretty small. 5 BY MR. TISI: 6 Q. Okay. And so the answer to 7 my question is, because of the results 8 that you got in your studies, you have 9 never done in your published literature a 10 full-blown Bradford Hill causation 11 analysis because you didn't get that far? 12 MS. MILLER: Objection. 13 That mischaracterizes the 14 testimony. 15 BY MR. TISI: 16 Q. If it is, correct me, 17 please. 18 A. No. In order to establish 19 causation, you have to start with that. 20 And if it doesn't show that there's 21 causation, why would you write in sort of 22 a whole article, you know, we did 23 Bradford Hill criteria? I mean, I'm 24 saying that the same methodology is used</p>	<p style="text-align: right;">Page 269</p> <p>1 I can point out to numerous 2 publications, like, for clinical 3 trials. Typically, the first 4 author is the chair of the 5 clinical trial. The second author 6 is the -- the statistician that is 7 on the clinical trial, to 8 recognize their role in the design 9 of the study, as well as the 10 interpretation of the data. 11 BY MR. TISI: 12 Q. My question is -- 13 MS. MILLER: She's answering 14 your question. 15 MR. TISI: You're not 16 answering my question, Doctor, 17 honestly. 18 MS. MILLER: She's doing her 19 best. 20 MR. TISI: She's not. 21 BY MR. TISI: 22 Q. I said in, how many -- very 23 few of these articles -- in fact, I think 24 I counted eight. I have to go back and</p>

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<p style="text-align: right;">Page 270</p> <p>1 check, it's certainly under ten, where 2 you were either the first or last author. 3 Would that be about accurate? 4 MS. MILLER: Objection. 5 THE WITNESS: Yeah, I -- I 6 don't know. I mean, if you say 7 you counted it, I can go through 8 and count. But I'm just not sure. 9 I'm trying to answer sort of what 10 my role is in these studies. 11 BY MR. TISI: 12 Q. It would -- 13 A. And again, you don't know 14 this field, but in clinical trials, I 15 would never be the first and last author 16 because I am not the study chair. 17 The role -- what shows the 18 contribution of me is the second 19 position, and there are many where I am 20 the second position. And in fact, on 21 things that have changed practice. 22 Q. You have criticized 23 Dr. Smith-Bindman and her meta-analysis, 24 correct?</p>	<p style="text-align: right;">Page 272</p> <p>1 meta-analyses that I can count. She has 2 six published in JAMA. JAMA is a high 3 impact journal, would you agree? 4 A. Yes, JAMA is a high impact 5 journal. 6 Q. Right. She has two 7 meta-analyses in high impact journals. 8 Can you tell me whether or not you've 9 ever published a meta-analysis in any 10 high impact journal? 11 A. Can you show me those 12 references to the meta-analyses that she 13 published? 14 Q. 47 -- 47 -- she or you? 15 A. Not me. Hers. 16 Q. I'm asking about yours. 17 MS. MILLER: But you asked 18 about -- 19 THE WITNESS: No, you asked 20 about her. 21 MS. MILLER: You said she 22 has six published in JAMA. Would 23 you agree? 24 MR. TISI: No, I said two.</p>
<p style="text-align: right;">Page 271</p> <p>1 A. I -- I show where I think 2 there are some limitations in her 3 analyses, yes. 4 Q. Well, you said that they 5 were flawed. I think that's -- you used 6 the word flawed. 7 A. I may have used the word 8 "flawed." 9 Q. Do you know that 10 Dr. Smith-Bindman, unlike yourself, is 11 actually submitting her analysis to peer 12 review. Does that surprise you? 13 A. I did not know that. 14 MS. MILLER: When you're 15 ready, they sometimes take away 16 the food away by 1:00. So we 17 should probably wrap up and take a 18 break. 19 MR. TISI: I'm almost done 20 with this section here. 21 MS. MILLER: Okay. 22 BY MR. TISI: 23 Q. So you've published. You've 24 been on articles where -- three</p>	<p style="text-align: right;">Page 273</p> <p>1 BY MR. TISI: 2 Q. No, I didn't ask -- I said I 3 will represent to you that she has two 4 published in JAMA. She has six 5 meta-analyses published total. 6 MS. MILLER: I'm looking at 7 the realtime. It says, "You have 8 published -- you've been on 9 articles or three meta-analyses 10 that I can count. She has six 11 published in JAMA. JAMA is a high 12 impact journal. Would you agree?" 13 BY MR. TISI: 14 Q. Okay. Well, let me rephrase 15 the question. She has six meta-analyses, 16 two published in JAMA. You would agree 17 that JAMA is a high impact journal? 18 A. Well, I just want to see -- 19 I want to see those citations -- 20 Q. I'm not asking you -- 21 A. -- because you're saying 22 she. I mean, does it -- where is she in 23 the author list. I don't know even what 24 you're --</p>

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<p>1 Q. Is that important?</p> <p>2 A. I don't know. I just want</p> <p>3 to see what the titles are of the --</p> <p>4 Q. Then let's talk about you.</p> <p>5 A. -- articles.</p> <p>6 Q. Let's talk about you. In</p> <p>7 your three published meta-analyses,</p> <p>8 Number 47, 68, and 142 on your CV, were</p> <p>9 you the lead designer of the study?</p> <p>10 A. I was --</p> <p>11 MS. MILLER: Do you want to</p> <p>12 see?</p> <p>13 BY MR. TISI:</p> <p>14 Q. 47, 68, and 142.</p> <p>15 A. Thank you. Yeah, yeah,</p> <p>16 yeah.</p> <p>17 MS. MILLER: Would it be on</p> <p>18 this list? I found the 47.</p> <p>19 THE WITNESS: No, it's not</p> <p>20 that list.</p> <p>21 MS. MILLER: There's so many</p> <p>22 lists.</p> <p>23 THE WITNESS: It would be my</p> <p>24 CV maybe? Is that what you're</p>	<p>1 MR. TISI: I understand.</p> <p>2 I'm almost done. The food is</p> <p>3 not --</p> <p>4 MS. MILLER: I think we've</p> <p>5 just been going an hour. It's a</p> <p>6 good time to break.</p> <p>7 MR. TISI: I understand.</p> <p>8 I'm just at the end of the --</p> <p>9 MS. MILLER: Okay. Great.</p> <p>10 MS. SHARKO: Did you miss</p> <p>11 me?</p> <p>12 BY MR. TISI:</p> <p>13 Q. The next one is which one,</p> <p>14 68?</p> <p>15 A. And I see that one.</p> <p>16 Q. And that's -- which one is</p> <p>17 that one? Is that O'Sullivan, or is that</p> <p>18 142?</p> <p>19 A. No, 68 is Witt, Gami,</p> <p>20 Ballman, Brown.</p> <p>21 Q. And the other one is -- 142</p> <p>22 is O'Sullivan.</p> <p>23 A. Yes.</p> <p>24 (Document marked for</p>
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<p>1 talking about my CV?</p> <p>2 MR. TISI: Let me see it.</p> <p>3 MS. MILLER: Is this the</p> <p>4 document? It's 47, Witt, Ballman.</p> <p>5 THE WITNESS: That's one.</p> <p>6 MS. MILLER: So then I think</p> <p>7 this is maybe the right list.</p> <p>8 THE WITNESS: Yeah, I see</p> <p>9 it.</p> <p>10 MS. MILLER: Okay. Great.</p> <p>11 THE WITNESS: Again, you see</p> <p>12 I'm second. So that means I</p> <p>13 played a very integral role in</p> <p>14 this --</p> <p>15 BY MR. TISI:</p> <p>16 Q. That's Number 47?</p> <p>17 A. Yep.</p> <p>18 Q. And what's that one called?</p> <p>19 A. "The Incidence of Stroke</p> <p>20 After Myocardial Infarction: A</p> <p>21 Meta-Analysis."</p> <p>22 MS. MILLER: Again, I just</p> <p>23 want to suggest that we break for</p> <p>24 lunch soon because --</p>	<p>1 identification as Exhibit</p> <p>2 Ballman-17.)</p> <p>3 BY MR. TISI:</p> <p>4 Q. I'm going to hand you</p> <p>5 O'Sullivan. Did you play a substantial</p> <p>6 role in the meta-analysis which is 142,</p> <p>7 the O'Sullivan meta-analysis?</p> <p>8 A. What do you mean by a</p> <p>9 substantial role?</p> <p>10 Q. Did you design it?</p> <p>11 A. I was part of the group, so</p> <p>12 this is actually a pooled analyses.</p> <p>13 Q. It says meta-analysis in the</p> <p>14 title.</p> <p>15 A. Yeah. So you can't get</p> <p>16 everything out of titles, right? So a</p> <p>17 pooled analysis is a type of</p> <p>18 meta-analysis. It's a much stronger</p> <p>19 meta-analysis in the sense that what</p> <p>20 happens is you get individual patient</p> <p>21 level data.</p> <p>22 So this is pooling data</p> <p>23 from, like, the largest clinical trials</p> <p>24 that were done in adjuvant trastuzumab,</p>

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<p style="text-align: right;">Page 278</p> <p>1 and that's Herceptin for women that have 2 HER2 positive breast cancer. I control 3 the data for one of the big trials in 4 trastuzumab. 5 And so I was part of this 6 group that just came together and said, 7 wow, we should use all this data, pool it 8 together to address a rare type of 9 situation, which was done here. 10 Q. Did you do any of the 11 writing of this? 12 A. I -- I did not do the first 13 draft, but I did go through and make 14 revisions and comments. 15 Q. Isn't it true that you were 16 identified as primarily the collection 17 and assembly of data? 18 A. That was probably the 19 biggest role that I played in this study. 20 But I did -- yeah. 21 Q. Isn't that kind of what 22 you -- isn't that kind of what you've 23 done in the meta-analysis that you've 24 done, you're primarily the collection of</p>	<p style="text-align: right;">Page 280</p> <p>1 times. 2 BY MR. TISI: 3 Q. I'm asking you -- I'm asking 4 you whether or not you, by training and 5 experience, you think you have better 6 qualifications than Dr. Smith-Bindman? 7 A. I can't answer that. I 8 mean, I don't know. I mean, I would have 9 to go through and look at all -- at all 10 the stuff she's done. My only exposure 11 to her was the study that she's done, and 12 I don't think it was done particularly 13 well. 14 Q. The one she's submitting for 15 peer review? 16 A. Has she submitted it? Has 17 it been published? I wonder if it will 18 be published actually. 19 Q. Well, we'll have to see how 20 that goes. 21 MR. TISI: I am -- this is 22 a -- this is a good time for 23 lunch. 24 THE VIDEOGRAPHER: The time</p>
<p style="text-align: right;">Page 279</p> <p>1 data? 2 A. No, that's not true. 3 Q. Okay. So the other two 4 would be ones that you did more than 5 that, 47 and 58? 6 A. Well, you know -- 7 Q. 47 and 68. Excuse me. 8 A. Yes, I mean I -- I -- I -- 9 it's sort of -- it's a whole 10 collaborative thing. It's not like, you 11 know, this is a service that you're 12 trying to imply. It's a scientific 13 endeavor that's done as a collaborative 14 experience among various different 15 scientists with different expertise. 16 Q. Do you think you're as -- 17 just have one -- do you think you have 18 the same qualifications or better than 19 Dr. Smith-Bindman in doing a 20 meta-analysis? 21 MS. MILLER: Objection. I 22 think she testified that she 23 wasn't testifying about other 24 witnesses' qualifications three</p>	<p style="text-align: right;">Page 281</p> <p>1 is 12:49 p.m. Off the record. 2 - - - 3 (Lunch break.) 4 - - - 5 AFTERNOON SESSION 6 - - - 7 THE VIDEOGRAPHER: We are 8 back on the record. The time is 9 1:27 p.m. 10 - - - 11 EXAMINATION (Cont'd.) 12 - - - 13 BY MR. TISI: 14 Q. Doctor, before lunch -- I 15 want to finish up talking about your 16 qualifications. I want to move onto a 17 new topic here. 18 I want to ask you about two 19 questions, two or three questions I think 20 about Bradford Hill, and then we're going 21 to move on to your analysis. 22 A. Okay. 23 Q. Okay. Just so we know, 24 we'll talk about case -- case-control and</p>

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<p style="text-align: right;">Page 282</p> <p>1 cohort studies, just to kind of give you 2 a little bit of roadmap of where I'm 3 going. All right? 4 Bradford Hill, we can both 5 agree, we've used the word criteria, but 6 we both agree that these are -- this 7 is -- these are guidelines, correct? 8 A. I call it a framework. 9 Q. Okay. And just to be clear, 10 you use the word criteria. And I've 11 actually used it in my -- in my 12 questions. 13 When you use the word 14 criteria, we really are talking about, 15 these are different considerations that 16 should be looked at when you're looking 17 at the question of causation generally. 18 A. Yeah. So Bradford Hill has 19 nine different considerations that one 20 should consider with -- within the 21 framework of doing a Bradford Hill 22 analysis. 23 Q. Right. And just -- just to 24 be clear for the record, this isn't like</p>	<p style="text-align: right;">Page 284</p> <p>1 being used. 2 BY MR. TISI: 3 Q. And that's a -- that's a 4 methodologic flaw that you identified 5 that you think the plaintiffs' experts 6 didn't adequately consider the -- that -- 7 that cohort studies are higher on the 8 evidentiary ladder than case-control 9 studies, true? 10 A. I -- I believe that some of 11 plaintiffs' experts just sort of, just 12 flat out say that case-controlled studies 13 have the higher evidence than the cohort 14 studies. 15 Q. Let's talk about that for a 16 moment. On Page 3, on your -- your -- 17 excuse me. On your conclusion, we -- it 18 talks about the levels of evidence. Do 19 you remember, you -- we -- we talked 20 about that, that's Exhibit Number 2. You 21 actually mention it in your conclusion, 22 right? 23 A. So I'm sorry, where -- 24 where --</p>
<p style="text-align: right;">Page 283</p> <p>1 a cookbook or a mathematical formula. 2 Bradford Hill is -- is a balancing of the 3 evidence using that -- that framework as 4 a guideline? 5 MS. MILLER: Objection. 6 THE WITNESS: So I mean, 7 research is not a cookbook. But, 8 you know, one can apply Bradford 9 Hill -- I mean I think there's 10 incorrect ways of applying 11 Bradford Hill. 12 BY MR. TISI: 13 Q. Okay. And one of them, 14 you -- you -- and this leads into my next 15 question is, you believe that there are 16 levels of evidence that trump other 17 levels of evidence, generally speaking? 18 MS. MILLER: Objection. 19 THE WITNESS: In the 20 epidemiology literature, it's 21 pretty much I think agreed upon 22 that there are -- there are 23 different levels of evidence based 24 upon what type of study design is</p>	<p style="text-align: right;">Page 285</p> <p>1 Q. It's the second sentence, it 2 says, "In assessing studies for the level 3 of evidence in the data." 4 A. Okay. 5 Q. And we agreed -- 6 A. Yeah. So I used that word. 7 Yeah, I used that word. 8 Q. And we agreed before that 9 the level of evidence you were talking 10 about was prospective case-controlled -- 11 prospective cohort studies versus case 12 controls? 13 A. No, no, no. That's not 14 correct here. 15 Q. Okay. 16 A. This here, as I'm looking at 17 the evidence in totality across 18 everything I looked at. 19 Q. Okay. But below in the -- 20 on Page 53 you say, "Cohort studies 21 provide stronger evidence than do 22 case-control studies." 23 It's near the -- like five 24 lines --</p>

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<p style="text-align: right;">Page 286</p> <p>1 A. "Cohort studies provide 2 stronger evidence do" -- "than do 3 case-control studies." 4 That's stated there, yes. 5 Q. Okay. And you think that's 6 a general epidemiologic principle, 7 correct? 8 A. I do. 9 Q. And you repeat that 10 repeatedly throughout your report, 11 correct? 12 A. I -- I may state it several 13 times. 14 Q. Okay. Let's -- let's look 15 at them. 16 First of all, if you go to 17 Page 4 of your report, you talk about the 18 levels of evidence with increasing 19 reliability. It says, on -- "Figure 1 20 illustrates the level of evidence with 21 each trial design with increasing 22 evidence moving up the pyramid." 23 Do you see that? 24 A. I do see that.</p>	<p style="text-align: right;">Page 288</p> <p>1 Q. And under that are 2 case-control studies? 3 A. Yes. 4 Q. And under that are case 5 reports and case series? 6 A. Yes. 7 Q. Okay. And you have kind of 8 bright lines between the two, to really 9 differentiate for the reader, that there 10 is -- these are established principles, 11 correct -- 12 MS. MILLER: Objection. 13 BY MR. TISI: 14 Q. -- that -- that cohort 15 studies are -- are better than 16 case-control studies, are better than 17 case reports and case series, et cetera? 18 MS. MILLER: Objection. 19 THE WITNESS: I -- I don't 20 think I said better. And I think 21 the lines are there just -- just 22 so there has -- there doesn't have 23 to be lines there. 24 And what it's trying to show</p>
<p style="text-align: right;">Page 287</p> <p>1 Q. And then you have a pyramid? 2 A. I do. 3 Q. Okay. And what is the 4 purpose of this illustration that you 5 included in your report on Page 4? 6 A. Just -- just to -- to give a 7 visual for how the different study 8 designs compared to each other in terms 9 of -- of the level of evidence that 10 epidemiologists believe are -- are 11 conveyed in each of the different types 12 of studies. 13 Q. And below randomized 14 controlled trial -- there's randomized 15 and there's meta-analysis, and by that 16 you mean meta-analysis of controlled 17 trials, correct? 18 A. Yes. 19 Q. Okay. And then underneath 20 are RCTs? 21 A. Mm-hmm. 22 Q. Okay. And under that are 23 cohort studies? 24 A. Yes.</p>	<p style="text-align: right;">Page 289</p> <p>1 is the level of evidence contained 2 in those. I don't -- I mean, I 3 don't know what you mean by 4 better. 5 BY MR. TISI: 6 Q. Well, okay. Cohort studies, 7 according to your chart, are more 8 reliable than case-controlled studies? 9 A. Again, they -- they have a 10 higher level of evidence. I don't -- I 11 don't know if I would say reliable is the 12 same as level of evidence. 13 Q. Okay. Now, you don't have 14 any citation for this, for this chart, do 15 you? 16 Did you create this or is 17 this from some other place? 18 A. I -- I have seen this in 19 numerous, numerous different places, but 20 I made this particular figure by myself. 21 Q. Okay. So there's no 22 citation for this? 23 A. Not in this document, but 24 there is in the epidemiology literature.</p>

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<p>1 Q. Okay. Well, there's no 2 citation for this, correct? 3 MS. MILLER: Objection. 4 Asked and answered. 5 BY MR. TISI: 6 Q. Because what I'm going to 7 ask -- I'm going to ask you questions 8 about that, but you did not provide a 9 citation for Figure 1 -- 10 MS. MILLER: Objection. 11 BY MR. TISI: 12 Q. -- where you got that 13 statement from? 14 MS. MILLER: I'm sorry, I 15 just always think you're done with 16 your question so I object, and 17 then you keep going. That's now 18 three questions and it's one 19 question. We're having the same 20 ongoing issue that we had before. 21 Objection to all three parts 22 of that question. 23 BY MR. TISI: 24 Q. Okay. Doctor --</p>	<p>1 you know, how the P-values were -- 2 were calculated because it's -- 3 it's sort of a given -- 4 BY MR. TISI: 5 Q. Okay. 6 A. -- knowledge. 7 Q. On Page 7 of your report. 8 And I'm just going to read a couple 9 places where you make this point. 10 On Page 7, 3.3, you say, 11 "Generally in my experience, prospective 12 cohort studies yield a higher level of 13 evidence than case-control studies." 14 That's the first sentence 15 in -- 16 A. That is what it says there. 17 Q. Okay. Could you just put a 18 line next to that so we can -- we may 19 come back to that. Could you just put 20 a -- 21 A. May I write? 22 Q. Yeah, you can write on that. 23 MS. MILLER: I think she 24 can --</p>
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<p>1 MS. MILLER: So which 2 question is -- 3 BY MR. TISI: 4 Q. Doctor, do you have a 5 citation to this chart? 6 A. I made the chart up myself. 7 And -- and it is just an underlying 8 epidemiological principle, so it -- it 9 doesn't have a citation. It would be 10 like cite -- citing what a T test is. 11 Q. Okay.4? 12 A. It's sort known through the 13 literature as to this is... 14 Q. Okay. So your -- so your -- 15 your view if it's a general principle, 16 you don't have to cite something to 17 support it? 18 MS. MILLER: Objection. 19 THE WITNESS: You know, 20 again, it's -- it's a general 21 principle and, you know, and when 22 one is talking about odds ratios 23 or P-values and things like that, 24 we, you know, we're not citing,</p>	<p>1 BY MR. TISI: 2 Q. Yeah, would you, please? 3 Yes, it's an exhibit. Thank you. 4 MS. MILLER: Why don't we 5 just use a sticky? 6 MR. TISI: No, because I'm 7 going to -- I want a record of 8 what we did. 9 BY MR. TISI: 10 Q. So on page -- and there's no 11 citation -- 12 MS. MILLER: She is not 13 creating an exhibit here. 14 MR. TISI: Yeah, she is. 15 MS. MILLER: No. 16 MR. TISI: Yeah, she is. 17 MS. MILLER: Well, I am 18 objecting to that. 19 MR. TISI: You can object to 20 it. 21 MS. MILLER: If you want 22 stickies she can put stickies. 23 MR. TISI: You can object to 24 it. You can object to it, and</p>

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<p>1 we'll ask the -- we can take a 2 break and call the judge if you 3 want to do that. 4 MS. MILLER: Any time you 5 want. You seem to be threatening 6 that a lot. 7 MR. TISI: Do you want to do 8 that? 9 MS. MILLER: It's up to you. 10 MR. TISI: Do you want to do 11 that? Because I'm happy to -- 12 because I would like to draw on 13 that exhibit there where she -- 14 MS. MILLER: Well, she's 15 already drawn it. I will see what 16 else you ask of her. 17 BY MR. TISI: 18 Q. On Page 17, second full 19 paragraph. 20 A. Yes. 21 Q. Does it say -- does it say, 22 "When the results across study designs 23 are not consistent, i.e., case-control 24 study reports a statistically significant</p>	<p>1 going off of Figure 1, which is a 2 generally accepted principle in 3 epidemiology. 4 Q. Okay. But the answer there 5 is there's no citation there, right? 6 MS. MILLER: Objection. 7 THE WITNESS: There's no 8 citations for many things that are 9 general sort of principles of 10 epidemiology or other facts. 11 BY MR. TISI: 12 Q. Please go to Page 26, 13 please. 14 A. There's no citation there. 15 I take it back. But I do have citations 16 in -- and if you give me a minute to 17 look, I can -- 18 Q. No, I want to see -- 19 A. -- find citations where 20 there's a higher level of evidence -- 21 Q. I'm going through every 22 place where you've said it. And I want 23 to put this, Doctor. First, follow me. 24 MS. MILLER: Chris, excuse</p>
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<p>1 association, but cohort studies do not, 2 the study with the accepted higher level 3 of evidence is the cohort study because 4 it eliminates bias such as recall bias"? 5 A. That's what it states. 6 Q. Okay. Can you put a little 7 star next to that, please? 8 MS. MILLER: A star. 9 BY MR. TISI: 10 Q. Or a whatever. So -- I want 11 to be able to come back to it. Could you 12 do that, ma'am? 13 A. I'll remember where it is. 14 Q. No, could you just put a -- 15 please, would you do what I've asked, 16 please? 17 MS. MILLER: I have a 18 standing objection to this. I 19 think this is improper. 20 MR. TISI: You can object. 21 BY MR. TISI: 22 Q. On Page 26 -- and of course 23 you do not have a cite to that? 24 A. As I mentioned, this is</p>	<p>1 me. 2 MR. TISI: I ask -- I'm 3 asking the questions. 4 BY MR. TISI: 5 Q. Is there a citation after 6 that statement? The answer is no. 7 The next one, on Page 26, do 8 you see that it says, "It is well 9 established as discussed above that there 10 are more potential or confounding 11 case-control studies compared to 12 prospective cohort studies since the 13 prospective cohort studies are not prone 14 to participant selection, recall bias 15 with respect to exposure, which is why 16 they're considered to yield stronger 17 level of evidence than case-control 18 studies." 19 Do you see that? 20 A. On Page 26? No, I -- 21 Q. Second sentence of the first 22 full paragraph. "It is well 23 established" -- 24 A. Which it says, "As discussed</p>

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<p style="text-align: right;">Page 298</p> <p>1 above." So I'm going to go and look at 2 the "as discussed above" for the 3 citations. 4 So I have a citation to a 5 book called case-control studies. And 6 actually my references are transposed 7 there. 8 That discusses sort of the 9 level of evidence. 10 Q. Okay. So you think that's 11 the citation. What is the name of that? 12 What is the name of that one? 13 A. So it's listed as six. But 14 it should be seven there, "Case-Control 15 Studies: Design, Conduct and Analyses." 16 Q. Okay. I'll look that up. 17 Let's go to page -- 18 A. And also -- I also think I 19 have more. Oh, it's in the meta-analyses 20 that we were talking about. And so 21 there's a Citation 23. And I say, "So 22 this is because, due to the effects of 23 confounding and bias, observational 24 studies may produce estimates that</p>	<p style="text-align: right;">Page 300</p> <p>1 A. "Cohort studies yield a 2 higher level of evidence. Hill observed, 3 'I would put myself at a good deal of 4 weight upon similar results reached in 5 quite different ways, i.e., prospectively 6 and retrospectively." 7 Q. But they're not -- you can 8 have prospective case-control studies and 9 you can have retrospective case-control 10 studies. You could have prospective -- 11 A. How can you have prospective 12 case-control studies? 13 Q. Actually, you're right. You 14 can have prospective and retrospective 15 cohort studies, correct? 16 A. It depends upon how you 17 define it. 18 Q. He didn't talk about 19 case-controls and cohorts, did he? 20 A. I don't know. I'll have to 21 look up Bradford Hill. 22 Q. Okay. But you do say, 23 without citation, "Cohort studies yield a 24 higher level of evidence," correct, on</p>
<p style="text-align: right;">Page 299</p> <p>1 deviate from a true causal." 2 That's -- that's 3 observational studies in general. 4 Q. But nothing saying that it's 5 a higher level of evidence? I'm looking 6 for a citation that says cohort studies 7 are a higher level of evidence as a 8 general rule than case-control studies. 9 A. So again, I think -- it is 10 implied throughout. 11 Q. It's implied, but it's not 12 cited. And I'm looking for a citation to 13 that. It's not only implied. Actually, 14 you come right out and say it several 15 times. 16 A. Yes. 17 Q. Okay. So let's go to Page 18 28, last paragraph, last sentence. 19 A. Yes. 20 Q. It says, "Cohort studies 21 yield a higher level of evidence." No 22 citation for that either? 23 A. I'm sorry. Last sentence? 24 Q. Cohort studies. Page 28.</p>	<p style="text-align: right;">Page 301</p> <p>1 Page 28? 2 A. There's no explicit citation 3 on -- for the sentence that you read. 4 Q. Let's go to Page 35. Third 5 paragraph, last sentence. "Now, the 6 cohort studies observed a dose-response 7 relationship. Cohort studies provide a 8 higher level of evidence than do 9 case-control studies." 10 (Brief teleconference 11 interruption.) 12 THE WITNESS: Yes, there's 13 no citation after that particular 14 sentence, I agree. 15 BY MR. TISI: 16 Q. Okay. So in this one 17 there's no citation to cohort studies 18 providing a higher level of evidence than 19 do case-control studies, true? 20 A. There's no citation after 21 that particular sentence. You are 22 correct. 23 Q. Okay. And you have a 24 statement in the conclusion that cohorts</p>

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<p>1 are better than case-control, and that 2 also doesn't have a citation, correct? 3 A. What conclusion? 4 Q. On the conclusion on Page 5 53. 6 A. I do not have a citation 7 after that sentence. 8 Q. Now, on Page 45, in your 9 criticism of Dr. Smith-Bindman, you say, 10 in the middle of the page, "As I said 11 above there is evidence in the literature 12 that cohort studies provide less biased 13 information than case-control studies, 14 and I have not found instance where 15 the -- instances where the opposite is 16 argued." 17 Do you see that? 18 A. Mm-hmm. 19 Q. Okay. And there's no 20 citation to that as well, right? 21 A. Well, if I didn't find any 22 instances where that has been showing, 23 there wouldn't be citations. 24 Q. Did you look?</p>	<p>1 conclusion, rely very heavily on the 2 concept that, as a general rule, cohort 3 studies are better than case -- 4 case-control studies; is that true? 5 MS. MILLER: Objection. 6 THE WITNESS: It's not a 7 concept. It is a generally 8 accepted and well accepted 9 principle of epidemiology that 10 there is more evidence in cohort 11 studies than there is in 12 case-control studies because they 13 eliminate confounding. 14 And I'm just -- I need to 15 look, and I'm sure there are some 16 citations here. 17 BY MR. TISI: 18 Q. Well, the only cite you 19 mention are -- are -- it's Number 7 in 20 your report, the case-control studies -- 21 A. Right, but buried within 22 some of these other studies there are 23 statements such as, you know, it was 24 thought that oral contraceptives, you</p>
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<p>1 A. I did. 2 Q. You did? 3 A. Yeah. I have not seen a 4 study that has said there is a higher 5 level of evidence in case-control studies 6 than there is in cohort studies as a 7 whole. 8 Q. Actually, I didn't -- 9 actually, I didn't say higher level. I 10 said that cohort studies are as a whole 11 better than case-control studies. 12 A. No. Can -- what -- was that 13 the question? 14 Q. The statement is, "I have 15 not found the opposite to be true." 16 A. Exactly. And I don't have a 17 citation for "I have not found the 18 opposite to be true," because -- because 19 there is no literature that says the 20 opposite is true. 21 Q. Okay. The truth is that 22 your methodology, your opinions -- and 23 we've gone through several places in your 24 report -- rely very heavily on, and your</p>	<p>1 know, cause breast cancer based on 2 case-control studies, but then when 3 cohort studies were done, the opposite 4 was found due to the fact that they are a 5 lower level of evidence and biases and 6 confounding -- 7 Q. Are there other -- 8 A. -- in case-control studies. 9 Q. I apologize. 10 Are there other instances 11 where case-control studies have found the 12 real cause that cohorts haven't? 13 A. I don't know off of the top 14 of my head. 15 Q. But you know full well that 16 the current view in epidemiology is that 17 evidentiary period does not provide a 18 bright line between -- between 19 case-control and cohorts, don't you? 20 MS. MILLER: Objection. 21 THE WITNESS: Can you show 22 me where -- where getting you're 23 that information and why I should 24 know full well?</p>

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<p>1 BY MR. TISI: 2 Q. Let's start with your own 3 statement in the Viagra litigation. 4 Okay. 5 Let's -- let me show you 6 what I have marked as Exhibit Number 21. 7 (Document marked for 8 identification as Exhibit 9 Ballman-18.) 10 BY MR. TISI: 11 Q. Do you remember -- do you 12 remember -- 13 MR. SOILEAU: This is not 14 going to be 21 in this deposition. 15 MR. TISI: I'm sorry. For 16 the record, this is 18. 17 BY MR. TISI: 18 Q. And you have a -- do you 19 recall having a section in your Viagra 20 report which talks about levels of 21 evidence? 22 A. Not off of the top of my 23 head. I need to see it. 24 MS. MILLER: Is this the</p>	<p>1 for the record what you wrote in Viagra? 2 A. Yeah, this is -- this is 3 very abbreviated. Because I see I have a 4 section on randomized clinical trials 5 right here -- 6 Q. I'm asking you what you 7 read -- can you read -- can you read what 8 you wrote in Viagra? 9 MS. MILLER: Objection. 10 THE WITNESS: Read what? 11 BY MR. TISI: 12 Q. Read where it says levels of 13 evidence. Section B. There's a full 14 paragraph under levels of evidence. 15 Could you read what it says? 16 A. Sure. "Cancer epidemiology 17 attempts to identify risk factors that 18 are causative agents of cancer. Knowing 19 what causes a cancer may lead to 20 therapies that benefit patients and/or 21 strategies to minimize the exposure to a 22 risk. There are different levels of 23 evidence for determining whether a factor 24 is causal based on the underlying study</p>
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<p>1 whole report or just a portion of 2 the report? 3 MR. TISI: It's a portion of 4 the report. 5 MS. MILLER: Yeah, I don't 6 think that's right. I think that 7 you need to give her the whole 8 report. 9 MR. TISI: You can object -- 10 you know, you haven't even looked 11 at it. 12 MS. MILLER: Would you like 13 a whole report? 14 THE WITNESS: I would like 15 the whole report. 16 MR. TISI: Okay. Let me -- 17 you may like it. You can use your 18 time to do that. 19 BY MR. TISI: 20 Q. Doctor, I'm -- there's a 21 section in here, full paragraph on levels 22 of evidence. Do you see that? 23 A. Yes. There is a -- yes. 24 Q. Okay. Would you please read</p>	<p>1 design. A recognized ranking of common 2 study designs from the greatest level of 3 evidence to lowest is, one, randomized 4 clinical trials, two, cohort and 5 case-control studies, and three, case 6 reports and case series." 7 Then I go on and -- 8 Q. And just -- just -- 9 A. -- I list Number 1 -- 10 Q. I just asked you -- I simply 11 just -- 12 A. I -- I'm not finished. 13 Please, can you let me finish. Please. 14 Q. No. I asked you to read in 15 the record. Your lawyer if they want to 16 can do that. Okay? And I'm going to -- 17 MS. SHARKO: No, she has the 18 right to finish her answer, 19 Mr. Tisi, and you know that -- 20 MR. TISI: Who is -- who 21 is -- she has a right -- I asked 22 her to read the paragraph. 23 MS. SHARKO: You know that. 24 MR. TISI: That is -- to my</p>

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<p>1 knowledge --</p> <p>2 MS. SHARKO: What kind of</p> <p>3 question is that? A reading test?</p> <p>4 MR. TISI: I asked -- yes.</p> <p>5 That's what I asked her to do, and</p> <p>6 she read it. Thank you.</p> <p>7 THE WITNESS: But this</p> <p>8 misrepresents what this --</p> <p>9 MS. SHARKO: No, but she has</p> <p>10 the right --</p> <p>11 THE WITNESS: -- this</p> <p>12 paragraph is saying, because it's</p> <p>13 incomplete and taken out of</p> <p>14 context.</p> <p>15 BY MR. TISI:</p> <p>16 Q. I'm going to --</p> <p>17 A. And I see that you've</p> <p>18 provided -- it says Number 1, randomized</p> <p>19 clinical trials, and then -- and then it</p> <p>20 goes over on the next page. And then it</p> <p>21 stops because I'm sure I have a section</p> <p>22 on -- on case-control studies and a</p> <p>23 section on cohort studies, and it's</p> <p>24 consistent with what I say here.</p>	<p>1 Have you looked in textbooks to see</p> <p>2 whether that is true?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. I'm going to show you</p> <p>5 Dr. Rothman's textbook -- textbook on --</p> <p>6 on epidemiology.</p> <p>7 A. The whole textbook?</p> <p>8 Q. I'm showing you the entire</p> <p>9 chapter. The entire chapter.</p> <p>10 A. And the table of contents?</p> <p>11 MR. TISI: I can give --</p> <p>12 actually, I can give you the whole</p> <p>13 book. Let's do this.</p> <p>14 BY MR. TISI:</p> <p>15 Q. And if you feel like you</p> <p>16 need to look at the book, I'm happy to do</p> <p>17 it.</p> <p>18 MS. MILLER: I don't think</p> <p>19 there's any reason to take that</p> <p>20 tone with the witness --</p> <p>21 MR. TISI: I mean, you know,</p> <p>22 honestly --</p> <p>23 MS. MILLER: We've been very</p> <p>24 polite in these depositions. This</p>
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<p>1 Q. But you lump them --</p> <p>2 A. They are lumped together --</p> <p>3 Q. But you -- Doctor, this</p> <p>4 isn't -- this really isn't an argument.</p> <p>5 I'm asking you whether for the purposes</p> <p>6 of your Viagra case, where you describe</p> <p>7 the level of evidence, instead of five</p> <p>8 levels, you describe three.</p> <p>9 A. I think that is a</p> <p>10 mischaracterization --</p> <p>11 Q. Okay.</p> <p>12 A. -- because this is not</p> <p>13 complete.</p> <p>14 Q. All right.</p> <p>15 A. That they are put together</p> <p>16 because they are both observational</p> <p>17 studies, and then I'm sure I have a</p> <p>18 separate section that talks about the</p> <p>19 different aspects of clinical -- of</p> <p>20 case-control studies and cohort studies,</p> <p>21 and say essentially the same thing</p> <p>22 because it's an accepted underlying</p> <p>23 epidemiology principle.</p> <p>24 Q. So let me ask you this.</p>	<p>1 is the first deposition that I'm</p> <p>2 aware where the -- where the</p> <p>3 lawyer has been so rude to the</p> <p>4 witness.</p> <p>5 MR. TISI: I don't think I'm</p> <p>6 being rude at all. I don't think</p> <p>7 I'm being rude at all.</p> <p>8 Okay.</p> <p>9 MS. SHARKO: Maybe not by</p> <p>10 your standards.</p> <p>11 MR. TISI: Certainly not by</p> <p>12 your standards.</p> <p>13 MS. SHARKO: I would</p> <p>14 disagree with that.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Okay. Chapter -- I have the</p> <p>17 book. I'll give you the book.</p> <p>18 For the record, I'm going to</p> <p>19 have this marked as Exhibit Number 19.</p> <p>20 (Document marked for</p> <p>21 identification as Exhibit</p> <p>22 Ballman-19.)</p> <p>23 BY MR. TISI:</p> <p>24 Q. I'm looking at Chapter 8.</p>

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<p style="text-align: right;">Page 314</p> <p>1 And I'm going to give you the exhibit 2 right in front of you. And you can look 3 at the book if you'd like. 4 Doctor? 5 A. Yes, I'm -- I'm -- 6 Q. I have -- I'd like you to 7 look at the exhibit. You can look at the 8 book if you need to -- 9 A. I'm sorry, did -- did you 10 hand it to me? 11 Thank you. 12 Q. Now, this is Chapter 8. 13 It's called "Case-Control Studies." 14 Do you see that? 15 A. It does say case-control 16 studies. 17 Q. And the first 18 paragraph introduces the concept. It 19 says, "In this chapter, we will review 20 case-control designs and contrast their 21 advantages and disadvantages with cohort 22 designs." 23 Do you see that? 24 A. I'm sorry. Which page?</p>	<p style="text-align: right;">Page 316</p> <p>1 the next paragraph. It says, "Cohort 2 studies are not immune from problems 3 often thought to be particular with 4 case-control studies. For example, while 5 a cohort study may gather information on 6 exposure for an entire source population 7 at the outset of the study, it still 8 requires tracing subjects to ascertain 9 exposure variation and outcomes." 10 Do you see that? 11 A. So I'm sorry. I'm trying to 12 take in a lot of information. I'm sorry. 13 I'm going to have to ask you to rephrase. 14 Q. Okay. Does he not say, 15 "Cohort studies are not immune from 16 problems often thought to be particular 17 to case-control studies"? 18 A. That's what that sentence 19 says. 20 Q. Next sentence, he gives an 21 example. "For example, while cohort 22 studies may gather information on 23 exposure for the entire source 24 population, at the outset of the study it</p>
<p style="text-align: right;">Page 315</p> <p>1 Q. First page. The first 2 paragraph just introduces the topic. 3 A. Yes. 4 Q. Last sentence says, "In this 5 chapter we will review case-control to 6 study designs and contrast their 7 advantages and disadvantages to cohort 8 designs." 9 Do you see that? 10 A. I see that. 11 Q. Okay. The next sentence in 12 the first paragraph. "Conventional 13 wisdom about case-control studies is that 14 they do not yield estimates of effect 15 that are as valid a measure obtained from 16 cohort studies. This thinking may 17 reflect a common misunderstanding in 18 conceptualizing case-control studies 19 which will be clarified later." 20 Do you see that? 21 A. I -- I see that, you read 22 that correctly. 23 Q. Okay. And then he 24 describes, so if you want to go down to</p>	<p style="text-align: right;">Page 317</p> <p>1 still requires tracing of subjects to 2 ascertain exposure variation and 3 outcomes." 4 Do you see that? 5 A. Yes, it does say that. 6 MS. MILLER: Do you want to 7 give her the time to actually read 8 this, instead of plucking out 9 sentences from it? 10 THE WITNESS: Yeah, I 11 mean -- 12 MS. MILLER: You are 13 plucking out one sentence from a 14 paragraph. 15 BY MR. TISI: 16 Q. I'm happy to do -- I'm just 17 asking whether -- where it says -- do you 18 agree with that statement? 19 MS. MILLER: But she has to 20 read the whole thing. 21 THE WITNESS: But I don't 22 know. 23 MR. TISI: No, she doesn't. 24 I'm asking her whether she agrees</p>

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<p style="text-align: right;">Page 318</p> <p>1 with that statement. 2 BY MR. TISI: 3 Q. Do you agree that, "Cohort 4 studies may gather information on 5 exposure for an entire source population 6 at the outset of the study and still 7 requires tracing of subjects to ascertain 8 exposure variations and outcome. If the 9 success of this tracing is related to the 10 exposure and the outcome, the resulting 11 selection bias will behave analogously to 12 the often raised concern of case-control 13 studies." 14 Do you agree with that or 15 disagree with that? 16 MR. LOCKE: Objection. 17 THE WITNESS: I cannot say 18 just off the fly like this because 19 I have to see where they're going 20 with this, if they are just sort 21 of setting up, you know, why are 22 people doing case-control studies 23 in the first place, because they 24 have, like, lower level of</p>	<p style="text-align: right;">Page 320</p> <p>1 identification as Exhibit 2 Ballman-20.) 3 BY MR. TISI: 4 Q. It's entitled "Six 5 Persistent Research Misconception." 6 Do you see that? 7 A. Yes, I do see that. 8 Q. Have you seen this article 9 before? 10 A. You know, I think in my 11 career I have seen this article before. 12 Q. Okay. And again, 13 Dr. Rothman you would agree, he's the 14 founder of the Journal of Epidemiology. 15 You understand that, correct? 16 MS. MILLER: Objection. 17 THE WITNESS: I have no idea 18 if he's the founder of the Journal 19 of Epidemiology. 20 BY MR. TISI: 21 Q. This is a fairly well known 22 article, correct? 23 A. I don't know that either. 24 Q. Okay. Well, let's look at</p>
<p style="text-align: right;">Page 319</p> <p>1 evidence than cohort studies. I 2 just -- I can't really comment if 3 I agree or disagree with that. 4 BY MR. TISI: 5 Q. Okay. You can't agree or 6 disagree with that statement. 7 A. Well, with the limited 8 information -- I'm given a couple 9 sentences that I'm asked to look at out 10 of an entire chapter that comes out of an 11 entire book, I do not feel that I can 12 give a complete and truthful answer. 13 Q. Let's see if this helps. 14 Okay. I'm going to show you an article 15 that Dr. Rothman wrote on this very 16 topic. 17 MS. MILLER: Are we done 18 with this exhibit? 19 MR. TISI: For now. You 20 can put it to aside. You can 21 leave the book there if you like 22 to. You can refer to it if you 23 need to. 24 (Document marked for</p>	<p style="text-align: right;">Page 321</p> <p>1 Misconception Number 1, because actually 2 as opposed to reading the whole article, 3 which I'm more than happy to have you 4 take a look at if you'd like to, but 5 Misconception Number 1, would you read 6 that? He puts a bullet point there. 7 Would you please tell the judge and the 8 jury what he says is Misconception Number 9 1. Read that, please. 10 A. I'll read what he says. He 11 says, "The misconceptions are, number 12 one, there is a hierarchy of study 13 designs, randomized trials provide the 14 greatest validity" -- and he's talking 15 validity there -- "followed by cohort 16 studies, with case-control studies being 17 the least reliable." 18 Q. Okay. He calls that a 19 misconception, does he not? 20 A. You know, I don't know what 21 he means by validity, and I don't know 22 what he means by least reliable. I'm 23 talking about levels of evidence. So I 24 don't know if those terms mean exactly</p>

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<p>1 the same thing.</p> <p>2 Q. Okay. Let's see what he</p> <p>3 actually says. Does he say -- in the</p> <p>4 first paragraph he talks about RCT, first</p> <p>5 two paragraphs. Let's talk about the</p> <p>6 next paragraph.</p> <p>7 It says, "Both cohort and</p> <p>8 case-control studies will yield valid</p> <p>9 results when properly designed and</p> <p>10 carried out."</p> <p>11 Do you see that?</p> <p>12 A. Where it is again? Again,</p> <p>13 you're making me come -- you know, go</p> <p>14 through a whole lot of information and</p> <p>15 so --</p> <p>16 Q. Well, you know, I'm going to</p> <p>17 tell you, if you feel like you need to</p> <p>18 take a look at this entire misconception,</p> <p>19 feel free to do it.</p> <p>20 A. So, I mean, I'm surprised --</p> <p>21 I just want to point out a couple things</p> <p>22 and --</p> <p>23 Q. No, I don't -- there's no</p> <p>24 question pending. You said you wanted to</p>	<p>1 second-to-last paragraph on the first</p> <p>2 column.</p> <p>3 A. Okay. Thank you.</p> <p>4 Q. It says, "Discrepancies</p> <p>5 between cohort studies and case-control</p> <p>6 studies should not be explained away</p> <p>7 superficially by a presumed validity</p> <p>8 advantage for cohort studies over</p> <p>9 case-control studies."</p> <p>10 Does he not say that?</p> <p>11 A. That's what is written</p> <p>12 there.</p> <p>13 Q. Okay. And if you go --</p> <p>14 A. And I want to point out --</p> <p>15 and he goes on and says, "Properly</p> <p>16 designed case-control studies will</p> <p>17 produce the same results as properly</p> <p>18 designed cohort studies."</p> <p>19 So what that means is the</p> <p>20 studies need to not have recall bias and</p> <p>21 they need not to have selection bias,</p> <p>22 which is almost theoretically impossible</p> <p>23 to do.</p> <p>24 Also, this is the only</p>
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<p>1 take a look at it. Feel free to take a</p> <p>2 look at it, and I'll ask you questions</p> <p>3 about it.</p> <p>4 A. Okay.</p> <p>5 Q. I want to be fair.</p> <p>6 A. All right. Go ahead.</p> <p>7 Q. Does he not say, in the</p> <p>8 second paragraph, "Both cohort studies</p> <p>9 and case-control studies will yield a</p> <p>10 valid result when properly designed and</p> <p>11 carried out"?</p> <p>12 A. That's what he says.</p> <p>13 Q. Okay. Now, I'm going to</p> <p>14 read -- he says, "Similarly" -- on the</p> <p>15 next page, second-to-last paragraph,</p> <p>16 "Similarly, discrepancies between cohort</p> <p>17 studies and case-control studies should</p> <p>18 not be explained away superficially by a</p> <p>19 presumed validity advantage for cohort</p> <p>20 studies over case-control studies."</p> <p>21 True?</p> <p>22 A. I'm sorry. Where are you</p> <p>23 reading from again?</p> <p>24 Q. The next -- the</p>	<p>1 author out there that has written on</p> <p>2 this, is one textbook, same author, one</p> <p>3 paper, same author. And the author goes</p> <p>4 on to, say, "These misconceptions have</p> <p>5 been perpetuated in journals, classrooms</p> <p>6 and textbooks."</p> <p>7 And so I could do the same</p> <p>8 thing and find a vast majority more</p> <p>9 papers and textbooks and so forth that</p> <p>10 would dispute that.</p> <p>11 Q. But you didn't, Doctor. You</p> <p>12 didn't even cite it for any -- for any of</p> <p>13 the times. We went through your report,</p> <p>14 and you didn't cite one instance. You</p> <p>15 said one article that was in a different</p> <p>16 place, case-control -- case-control</p> <p>17 textbook. And I'm going to look that up.</p> <p>18 Okay. But other than that,</p> <p>19 you had no citations whatsoever, true?</p> <p>20 MS. MILLER: Objection.</p> <p>21 THE WITNESS: I disagree</p> <p>22 with that, because if we go back</p> <p>23 to -- to my report, I have -- I</p> <p>24 have like real evidence in the</p>

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<p style="text-align: right;">Page 326</p> <p>1 literature that shows that 2 case-control studies do, and 3 cohort studies do not -- when you 4 do -- have the opportunity to do a 5 randomized trial, it comes up with 6 a completely different conclusion. 7 And I have several 8 references that show that. And 9 that's real life data. That's not 10 purporting, you know, evidence 11 against what's a generally 12 accepted epidemiology principle. 13 BY MR. TISI: 14 Q. Let's look at the last 15 sentence in this section. It says, "When 16 properly designed" -- 17 A. And, you know, this says 18 it's a review too. It doesn't say it's a 19 research article. This is, like, I think 20 someone's opinion. I mean -- 21 Q. Like your report. Like your 22 report. Your report is your opinion. 23 MS. SHARKO: Don't interrupt 24 the witness.</p>	<p style="text-align: right;">Page 328</p> <p>1 I'm allowed to -- to give the 2 complete truth. 3 BY MR. TISI: 4 Q. Okay. 5 A. I feel like we're doing half 6 truths here. 7 Q. Okay. I'm perfectly happy 8 to stand on this article. 9 Let me -- let me look at the 10 last sentence. "When properly designed 11 case-control studies can achieve" -- "can 12 achieve the same excellent validity as 13 properly designed cohort studies, whereas 14 poorly designed trial can be unreliable. 15 The type of study should be not taken as 16 a guide to the study's validity." 17 Does he not say that? 18 A. He does say that there. 19 Q. Okay. Thank you. Do you 20 agree or disagree? 21 A. I disagree with his -- his 22 entire thing. I think for individual 23 studies there could be an individual 24 case-control study that might be better</p>
<p style="text-align: right;">Page 327</p> <p>1 BY MR. TISI: 2 Q. Your report is your opinion, 3 right? 4 MS. MILLER: Objection. 5 THE WITNESS: Those are two 6 different things. 7 BY MR. TISI: 8 Q. One is for litigation, and 9 one isn't? 10 MS. MILLER: Objection. 11 BY MR. TISI: 12 Q. Dr. Ballman, you know, 13 you're offering a lot of commentary of 14 things that I haven't asked. Okay? 15 I'm asking you, first of 16 all, this is published in the peer 17 reviewed literature, correct? 18 MS. MILLER: Objection. 19 MR. LOCKE: Objection. 20 THE WITNESS: So I think I'm 21 trying to give a complete and 22 truthful answer which I swore to 23 at the beginning of the 24 deposition, and I don't feel like</p>	<p style="text-align: right;">Page 329</p> <p>1 designed than an individual cohort study. 2 But I think as a body of 3 evidence as a whole, it is accepted as a 4 principle in epidemiology literature, 5 that what comes out of case-control 6 studies in total and what comes out of 7 cohort studies in total, are both under 8 randomized trials, and cohort studies 9 have less biases in terms of selection 10 biases and recall biases than do 11 case-control studies, which is why they 12 have a higher level of evidence. 13 Q. It has other biases too. 14 For example, if you only ask the 15 patient -- if the cohort study is not 16 designed to -- to look at a particular 17 question, and you only ask a person once 18 in 25 years whether they use talcum 19 powder, that can change over time, 20 correct? 21 A. So -- so what's the 22 question? 23 Q. The question is: That's a 24 bias as well, that would bias towards the</p>

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<p style="text-align: right;">Page 330</p> <p>1 null?</p> <p>2 MS. MILLER: Objection.</p> <p>3 BY MR. TISI:</p> <p>4 Q. If a patient, in a</p> <p>5 hypothetical cohort study, that was not</p> <p>6 designed specifically to look at whether</p> <p>7 talc causes ovarian cancer, and that</p> <p>8 patient -- and it's a 20-year study, and</p> <p>9 upon enrollment they are asked one time</p> <p>10 about their exposure to talc, is it</p> <p>11 possible that over two decades, the</p> <p>12 patient could change their behavior?</p> <p>13 MS. MILLER: Objection.</p> <p>14 There were three questions in</p> <p>15 there. I objected to the first.</p> <p>16 MR. TISI: There's not --</p> <p>17 that's fine. You can object --</p> <p>18 you can object to the question.</p> <p>19 MS. MILLER: Okay. I don't</p> <p>20 know what the question is.</p> <p>21 MR. TISI: That's fine.</p> <p>22 THE WITNESS: Can you ask</p> <p>23 one by one what -- what the --</p> <p>24 BY MR. TISI:</p>	<p style="text-align: right;">Page 332</p> <p>1 could -- could make comment on them.</p> <p>2 Q. In all the cohort studies</p> <p>3 regarding talc, the patients were asked</p> <p>4 on only one occasion whether they used</p> <p>5 talc early on in the study, correct?</p> <p>6 A. So the cohort --</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: So the cohort</p> <p>9 studies in talc were done in -- in</p> <p>10 cohorts of women that tended to be</p> <p>11 older. And -- and I can go</p> <p>12 through the different cohorts.</p> <p>13 BY MR. TISI:</p> <p>14 Q. I'm asking -- I didn't ask</p> <p>15 you to -- to recite me. I'm asking you,</p> <p>16 in each of those studies, the women</p> <p>17 enrolled in those studies were asked</p> <p>18 about talc exposure on one occasion,</p> <p>19 true?</p> <p>20 MR. LOCKE: Objection.</p> <p>21 THE WITNESS: So I was</p> <p>22 trying -- and your previous</p> <p>23 question I think was a little bit</p> <p>24 different and I was trying to</p>
<p style="text-align: right;">Page 331</p> <p>1 Q. You understand that there</p> <p>2 are biases that are also inherent in</p> <p>3 cohort studies as well?</p> <p>4 A. I -- I think I'm pretty --</p> <p>5 pretty clear that I think all</p> <p>6 observational studies have some sort of</p> <p>7 biases in them.</p> <p>8 Q. Right. And you have to</p> <p>9 consider all of them, correct?</p> <p>10 A. All of what?</p> <p>11 Q. All the biases and all the</p> <p>12 different kinds of studies.</p> <p>13 A. You have to consider -- I --</p> <p>14 I looked -- I don't know what that means.</p> <p>15 Q. You don't dismiss biases in</p> <p>16 cohort studies because they happen to be</p> <p>17 cohort studies, right?</p> <p>18 A. Again, it depends upon what</p> <p>19 the individual studies are and the</p> <p>20 question that is being addressed with the</p> <p>21 cohort study so that we can see what the</p> <p>22 individual biases are --</p> <p>23 Q. Right.</p> <p>24 A. -- and then, you know, one</p>	<p style="text-align: right;">Page 333</p> <p>1 answer that before you interrupted</p> <p>2 me with -- with the second</p> <p>3 question, and so --</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. Then let me withdraw</p> <p>6 the question.</p> <p>7 I'm going to ask you, can</p> <p>8 you name for me a cohort study --</p> <p>9 MS. MILLER: You just</p> <p>10 interrupted her again. She was</p> <p>11 like literally -- when she says</p> <p>12 "and so," you start talking. Let</p> <p>13 her finish her sentences.</p> <p>14 MR. TISI: I'm going to</p> <p>15 ask -- I'm going to ask -- I</p> <p>16 withdrew the question.</p> <p>17 BY MR. TISI:</p> <p>18 Q. My question is this --</p> <p>19 MS. MILLER: You can't just</p> <p>20 withdraw a question in the middle</p> <p>21 of an answer.</p> <p>22 BY MR. TISI:</p> <p>23 Q. Doctor, can you name me one</p> <p>24 cohort study involved in the talc science</p>

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<p>1 where the patients were asked more than 2 once about their talc exposure? 3 A. I cannot, but I'm not -- I'm 4 trying to say why that's not really a 5 relevant question. 6 Q. Okay. I just want to know 7 if they were asked more than once in any 8 of these studies. 9 A. They weren't asked more than 10 once in the case-control studies either. 11 Q. Well, that was only because 12 they were retrospective, right? 13 A. Well, there are reasons why 14 that asking only once in the cohort study 15 also is not entirely relevant. 16 Having to do with at the age 17 that women generally start using talc, 18 which is early adulthood, and the fact 19 that it's a habitual use and it's very 20 unlikely that a woman age, say 55, who 21 hadn't been using talc would all of the 22 sudden start using talc. 23 Q. Are you -- do you think that 24 you're a better qualified epidemiologist</p>	<p>1 idea and I don't know what the 2 relevance is in terms of -- of me 3 having issues -- or the 4 limitations of this particular 5 study. 6 BY MR. TISI: 7 Q. Well -- well, then let me -- 8 let me -- 9 MR. SOILEAU: Let me do this 10 and fix this, because we may have 11 gotten off. I don't think -- 12 MS. SHARKO: I thought only 13 one person -- 14 MR. SOILEAU: I'm doing 15 exhibits. I'm not asking 16 questions. 17 MR. TISI: It's an exhibit 18 issue. 19 MS. SHARKO: But I'm happy 20 to have you talk. That's okay. 21 MR. SOILEAU: I'm just going 22 to -- I think we agreed that we 23 had 18 as the Viagra report, 19 as 24 Chapter 8 of the Rothman text.</p>
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<p>1 than Ken Rothman is? 2 MR. LOCKE: Objection. 3 MS. MILLER: Objection. 4 What's with these questions? 5 THE WITNESS: I'm not 6 speaking on -- I'm not speaking on 7 qualifications or not. 8 I'm speaking on the fact 9 that there -- this is probably one 10 of the only papers that -- that 11 takes this stance that the general 12 accepted principles of 13 epidemiology are wrong. 14 BY MR. TISI: 15 Q. Do you know -- do you know 16 that Dr. Rothman was actually -- unlike 17 you, Dr. Rothman was actually asked by 18 the talc industry, including Johnson & 19 Johnson, to consult for them on the 20 talc-ovarian cancer association, did you 21 know that? 22 MR. LOCKE: Objection. 23 MS. MILLER: Objection. 24 THE WITNESS: I -- I have no</p>	<p>1 And I do not believe in the 2 record that the "Six Persistent 3 Research Misconceptions" that has 4 been discussed over the last pages 5 with the witness was actually 6 identified by number. 7 It has a sticker on it 8 that's wrong. It should be 9 Exhibit 20. 10 MS. MILLER: It says 19. Do 11 you want to make it 20? 12 MR. SOILEAU: Yeah, here's a 13 sticker. You can just stick it 14 over the top of it. 15 MS. MILLER: I wrote 20 16 right over it. 17 MR. SOILEAU: Okay. Very 18 good. And I apologize for 19 interrupting. 20 (Document marked for 21 identification as Exhibit 22 Ballman-21.) 23 MR. TISI: I'd like to show 24 you Exhibit Number 24.</p>

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<p>1 MS. MILLER: Wait. 21? 2 MR. TISI: 21. I'm sorry. 3 21. 4 MS. MILLER: You just 5 skipped 21, 22, 23. 6 MR. TISI: I'm sorry. 7 You're right. 8 BY MR. TISI: 9 Q. I'm going to represent to 10 you, Doctor, that Dr. Rothman and his 11 colleagues were asked to draft a report 12 for the national toxicology program in 13 2000 related to talc and ovarian cancer. 14 Have you seen this before? 15 A. Now is this published 16 somewhere? 17 Q. It was for the talc industry 18 including Johnson & Johnson. They 19 actually contributed to paying for it. 20 MR. LOCKE: Objection. 21 THE WITNESS: Sort of like 22 an expert report is in litigation? 23 BY MR. TISI: 24 Q. Sort of like -- absolutely</p>	<p>1 BY MR. TISI: 2 Q. Dr. Ballman -- 3 A. Yes. 4 Q. Unlike you, the scientists 5 at Johnson & Johnson, reached out to 6 Dr. Rothman in 2000 to draft a report 7 related to talc. Do you see that? 8 MR. LOCKE: Objection. 9 THE WITNESS: I -- can you 10 show me where this was 11 commissioned by Johnson & Johnson? 12 BY MR. TISI: 13 Q. I'm going to ask you to -- 14 I'm going to ask you to assume that, 15 because that's what the record will show. 16 This was a report submitted to the 17 National Toxicology Program on the part 18 of J&J? 19 MR. LOCKE: Objection. 20 BY MR. TISI: 21 Q. So let me -- let me show 22 you. 23 A. But where does it say that? 24 Where does it say the National</p>
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<p>1 absolutely. Sort of like that. Like 2 in -- 3 A. Like I've been asked to do? 4 Q. Like in real time, when the 5 issues were -- but the difference is, 6 see, they were asked by scientists at 7 Johnson & Johnson that they contacted 8 Dr. Rothman. It's the lawyers who 9 contacted you. 10 MS. MILLER: Objection. Was 11 that a question or are you just 12 giving speeches now? 13 MR. TISI: Well, no, she's 14 giving me a speech. 15 MS. MILLER: She's -- she's 16 sitting -- 17 MS. SHARKO: The witness -- 18 you know, it's really rude to call 19 a woman "she." 20 MR. TISI: Okay. 21 MS. SHARKO: Her name is 22 Dr. Ballman, and I would ask you 23 to treat the witness with respect. 24 MR. TISI: Okay.</p>	<p>1 Toxicology -- 2 Q. I'm asking you to assume it. 3 I'm allowed -- I'm allowed to ask you to 4 assume it. And counsel will correct me 5 later if I'm wrong. 6 A. Okay. 7 Q. The judge will strike me. 8 A. Okay. 9 Q. Okay? 10 MS. MILLER: I don't know if 11 the judge will actually strike 12 you. 13 BY MR. TISI: 14 Q. So on Page 3 -- on Page 3, 15 Dr. Rothman and his two colleagues -- 16 this wasn't just written by him, right? 17 A. But again, Dr. Rothman, it's 18 not independent of Dr. Rothman. 19 Q. Okay. That's fine. He 20 writes, "Exposure misclassification." 21 Do you see that section? 22 A. Yes. 23 Q. Okay. He says this: 24 "Nearly all the studies were case-control</p>

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<p style="text-align: right;">Page 342</p> <p>1 studies. It is commonly believed that 2 the validity of case-control studies is 3 worse than cohort studies, but this view 4 is mistaken." 5 Do you see that? 6 A. Yes, I do. 7 Q. Okay. And you disagree with 8 that? 9 A. Again, it's the same opinion 10 by the same individual and -- and I have 11 stated that the general principles of 12 epidemiology just does not support that. 13 Q. Okay. And the next 14 sentence, "The validity of a study design 15 depends on the specifics of the study 16 design. The nature of the data and the 17 nature of the hypothesis that the study 18 addresses." 19 Do you agree with that? 20 A. So now he's getting into 21 specifics. And I said I do agree that 22 one case-control study when compared to 23 one cohort study could be the case that 24 the case-control study is done a little</p>	<p style="text-align: right;">Page 344</p> <p>1 A. -- in terms of the habits. 2 I don't know, I haven't 3 looked at this literature. So I'd have 4 to look to see. Do most coffee drinkers 5 start when they're in their early 6 adulthood? Do most -- versus starting at 7 age 55. You know, it all depends on the 8 specifics of the study. 9 Q. The last two sentences here, 10 state what I think his -- his rule is. 11 "The effect of having a poor measure of 12 exposure will be considerable 13 nondifferential misclassification. A 14 type of error that introduces bias into 15 study results that tends to drive effect 16 estimates towards the null condition of 17 no effect. 18 "In contrast, it may be 19 possible to get more detailed information 20 from a study subject in a case-control 21 study which might avoid some of the 22 biases that would result in the cohort 23 study." 24 Do you see that?</p>
<p style="text-align: right;">Page 343</p> <p>1 better than the one cohort study. But 2 I'm arguing that -- I'm not arguing. I'm 3 sorry. 4 I'm just stating what the 5 general epidemiology principle is, is 6 that cohort studies, as a whole, have a 7 higher level of evidence for causality 8 than do case-control studies. 9 Q. He makes the point, if you 10 go next sentence -- he gives an example. 11 Next sentences says, "Although the 12 exposure information might be accurate at 13 the time that it was collected, the 14 exposure status of cohort members will 15 change with time and the initial measure 16 might only be poorly correlated with a 17 more meaningful measure." 18 Do you see that? 19 A. And -- but this has to do in 20 particular with coffee drinkers and a 21 one-time dietary assessment. So drinking 22 coffee or not is different from whether 23 one uses talcum powder or not -- 24 Q. Why?</p>	<p style="text-align: right;">Page 345</p> <p>1 MR. LOCKE: Objection to 2 form and to the reference to the 3 last two sentences. 4 MS. MILLER: I'm sorry. I 5 can't hear you. 6 MR. LOCKE: Objection to 7 form and the reference to the last 8 two sentences. 9 BY MR. TISI: 10 Q. Read it to yourself. Do you 11 agree or disagree with those last two 12 sentences? 13 A. It's just a very general 14 statement. I'm not sure what to agree 15 with or not to agree with. Again, I 16 think it depends very much on what the 17 question that's under consideration or 18 the study under consideration. And I 19 have to point out that says, "Which might 20 thus avoid some of the biases that would 21 result in a cohort study." 22 It doesn't say will. It 23 doesn't say anything definitive. It says 24 might.</p>

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<p style="text-align: right;">Page 346</p> <p>1 Q. But that's the point, 2 Doctor. And I'm really trying to back up 3 a little bit. 4 The point really here is, 5 what you really have to do is look at the 6 data and look at the studies, the cohort 7 and the case-control studies like you 8 said in your Viagra report. You look at 9 them together, and you decide which one 10 is better and which one is worse, true? 11 MS. MILLER: Objection. 12 That -- where did she say that in 13 the Viagra report that you should 14 look at them together? Can you 15 show that us? Because you showed 16 us part of the report. It didn't 17 say that. You're misrepresenting 18 her testimony. 19 MR. TISI: Counsel, please 20 stop. 21 MS. MILLER: You're 22 misrepresenting her report. This 23 is crazy. 24 MR. TISI: Stop. It is</p>	<p style="text-align: right;">Page 348</p> <p>1 did not show a statistically significant 2 result, whereas in the case-control 3 studies, some did, some didn't. And by 4 levels of -- as I say throughout my 5 report, as levels of evidence, one needs 6 to go with the cohort studies because 7 they have a higher level of evidence. 8 I'm not comparing one individual cohort 9 study to one individual case-control 10 study, where it might be the case that in 11 that particular comparison of two 12 different studies, maybe case-control was 13 done a little better than cohort. 14 Q. So -- okay. So we'd talked 15 about statistical significance in a short 16 while. 17 So but -- so what you're 18 saying is where there is a -- if you have 19 some studies that are cohort studies that 20 are not statistically significant and 21 some studies that are case-controls that 22 are statistically significant, the cohort 23 studies win? 24 MS. MILLER: Objection.</p>
<p style="text-align: right;">Page 347</p> <p>1 crazy. What is crazy is your 2 speaking/coaching objections. 3 That's crazy. 4 BY MR. TISI: 5 Q. Doctor, in your case -- in 6 your Viagra report you put case-control 7 and cohort studies in the same level of 8 evidence, did you not? 9 A. I do not believe I do. 10 Q. Okay. 11 A. I was just given one case 12 where -- where I -- no, I do not believe 13 I do. 14 Q. Okay. Now, isn't it true 15 that you're really, instead of just 16 blindly saying cohort is better than 17 case-control, you have to look at the 18 studies, how they're designed, what they 19 ask, and what the data shows; isn't that 20 true? 21 A. And that's what I did, and I 22 applied underlying epidemiological 23 principles. And so there were three 24 cohort studies, not just one. All three</p>	<p style="text-align: right;">Page 349</p> <p>1 THE WITNESS: I am -- not in 2 general. I am saying -- no, I did 3 not say that in general. I said 4 in the data and the analyses I 5 looked at, that was one component 6 of the whole totality of the 7 analyses. 8 BY MR. TISI: 9 Q. Okay. And statistical 10 significance was very important to you in 11 that way, in other words you kind of 12 put -- you saw whether there's a pattern. 13 You put together the statistically 14 significant results, the statistically 15 nonsignificant results, and you felt that 16 the statistically nonsignificant results 17 had the better reliability? 18 A. Again, I don't -- what I did 19 was I looked at the totality of the data. 20 I saw in the case-control studies, there 21 were some statistically significant and 22 some not statistically significant. 23 I did not group those with 24 the cohort studies which also were not</p>

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<p>1 statistically significant. So I do not 2 believe that I just sort of put all the 3 nonstatistically significant studies 4 together and the statistically 5 significant studies together. I do not 6 believe that's what I did. 7 Q. Do you think statistical 8 significance is the issue that is the -- 9 defines your opinion? In other words -- 10 in other words, where you feel that there 11 is inconsistency between the 12 observational data, because some studies 13 were not statistically significant and 14 others were. 15 MS. MILLER: Objection. 16 BY MR. TISI: 17 Q. True? 18 MS. MILLER: Objection. 19 THE WITNESS: I don't 20 believe that's what I stated. And 21 I believe I stated all along that 22 I did the Bradford Hill analyses. 23 You know, I looked at strength of 24 association. I looked at</p>	<p>1 The hospital-based controls, none of them 2 were statistically significant. And 3 those were case-control studies. You 4 know, so you look at the different study 5 designs, and you're getting different 6 sort of results, and that's an 7 inconsistency. 8 Q. Okay. And so they're 9 inconsistent in that some are 10 statistically significant and others 11 aren't? 12 MS. MILLER: Objection. 13 THE WITNESS: Again, taken 14 as a whole -- and I also talk 15 about the fact that if you look at 16 the magnitude of the estimates -- 17 BY MR. TISI: 18 Q. We'll talk about that. 19 A. -- that were produced -- 20 well, that has to do with consistency 21 too. 22 Q. I'm going to talk about -- I 23 need to -- 24 A. Well, no, you asked me if my</p>
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<p>1 consistency. And I made a note in 2 terms of consistency that there 3 was no consistency on many -- a 4 lack of consistency on many 5 different levels. 6 BY MR. TISI: 7 Q. Okay. Are you done? 8 MS. MILLER: Are you -- are 9 you still talking? 10 THE WITNESS: So this 11 factor -- so consistency is that, 12 you know, it needs to be multiple 13 studies across different locations 14 and populations, and study designs 15 have to show a similar association 16 between the exposure and outcome. 17 I would also note within the 18 case-control studies -- 19 BY MR. TISI: 20 Q. Can I -- can I ask you -- 21 A. -- the hospital-based -- 22 Q. -- a question here? Can I 23 ask you -- 24 A. I'm not finished, please.</p>	<p>1 consistency is just on the basis if -- 2 Q. I didn't. 3 A. -- there's statistical 4 significance or not. 5 Q. Doctor, you know, when I 6 ask -- when I ask a question, it involves 7 different variables, I get accused of 8 asking a compound question. So I'm 9 asking you one question at a time. 10 Is statistical significance, 11 when you looked at these studies overall, 12 did you find that the statistically 13 significant results were counter-balanced 14 by the statistically insignificant 15 results? 16 MS. MILLER: Objection. 17 THE WITNESS: I do not -- 18 I'm sorry. 19 I do not know what you mean 20 by counterbalance. 21 BY MR. TISI: 22 Q. In other words, did they 23 negate them? 24 MS. MILLER: Objection.</p>

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<p style="text-align: right;">Page 354</p> <p>1 THE WITNESS: That's not 2 what I said. 3 BY MR. TISI: 4 Q. Are they inconsistent with 5 them? Is it inconsistent that some 6 studies are statistically significant and 7 others aren't? 8 A. Again, consistency requires 9 that multiple studies across different 10 locations, populations, and study designs 11 show similar association between the 12 exposure and the outcome. 13 So I looked at case-control 14 studies, which is one design. And within 15 case-control studies you have 16 population-based case-control studies, 17 which is a design. You have 18 hospital-based control studies, which is 19 a design. 20 You also have cohort 21 studies, which is another different 22 design. 23 And when you look across 24 that, you do not come up with the same</p>	<p style="text-align: right;">Page 356</p> <p>1 A. I didn't say that they 2 shouldn't be done. But to be done 3 correctly and how to look at them 4 correctly, and -- is to do a separate 5 case -- meta-analyses of the case-control 6 studies, and a separate of the cohort 7 studies, and not just do one case -- or 8 one meta-analysis that combine both 9 together. 10 And a lot of the 11 meta-analysis, they do report out 12 separately for the case-control studies 13 and the cohort studies. 14 Q. But they do a meta-analysis 15 combining all the studies, every single 16 one of them combine all the studies? 17 MS. MILLER: Objection. 18 THE WITNESS: Yes. And I 19 have -- I do know that I have 20 citations in here somewhere that 21 shows that that is a problem with 22 meta-analysis. Because it lumps 23 over -- you won't be able to see 24 consistency or not, but you -- you</p>
<p style="text-align: right;">Page 355</p> <p>1 association. 2 Q. Isn't that why you do a 3 meta-analysis? 4 A. No. 5 Q. Okay. Well -- 6 A. Meta-analysis -- let me 7 answer -- finish that. 8 Meta-analyses are not meant 9 that if results differ from each other 10 you throw them all together to get a 11 result that you want. And in fact if 12 results are different from each other, 13 you shouldn't do a meta-analyses. That's 14 heterogeneity -- 15 Q. So you think -- 16 A. -- and that's going to lead 17 to an incorrect conclusion. 18 Q. So you think nobody -- 19 MS. MILLER: Are you done? 20 THE WITNESS: I'm done. 21 BY MR. TISI: 22 Q. So you think that -- there 23 are five or six meta-analyses. Do you 24 think those shouldn't have been done?</p>	<p style="text-align: right;">Page 357</p> <p>1 just have one result. So you 2 can't see where the results 3 differ. 4 BY MR. TISI: 5 Q. Now, in criticize -- 6 MS. MILLER: Is this a good 7 time for a break? 8 MR. TISI: No. Unless you 9 need it. Do you need it? 10 MS. MILLER: Do you need it? 11 THE WITNESS: I need it. 12 MS. MILLER: It's not about 13 me. It's about her. 14 MR. TISI: Absolutely. If 15 she needs it, she can always ask 16 for it. 17 THE WITNESS: Yeah, I'm 18 sorry. I was trying to be polite. 19 Thank you. 20 MS. MILLER: Yeah, she's 21 very polite. She's not going to 22 ask. 23 THE VIDEOGRAPHER: Stand by, 24 please. The time is 2:23 p.m.</p>

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<p style="text-align: right;">Page 358</p> <p>1 Off the record. 2 (Short break.) 3 THE VIDEOGRAPHER: Okay. We 4 are back on the record. The time 5 is 2:34 p.m. 6 BY MR. TISI: 7 Q. In your report -- Doctor, 8 we're talking about the talc studies 9 now -- you have some criticisms of the 10 plaintiffs' experts in how they addressed 11 the biases in the cohort studies and you 12 give your opinions about them, and it's 13 pretty clear in your report. You know 14 that section, correct? 15 MS. MILLER: Is that a 16 question? 17 MR. TISI: Yes. 18 THE WITNESS: Can you point 19 me to the section, please? 20 BY MR. TISI: 21 Q. Sure. I'm happy to do that. 22 On Page 28. Do you see you're addressing 23 the issues that the plaintiffs' experts 24 raise about the cohort studies and you</p>	<p style="text-align: right;">Page 360</p> <p>1 A. It's why I disagree with the 2 methodology. 3 Q. Okay. And for the record, 4 the cohort studies are what? Gertig, 5 Gates, Houghton and Gonzales? 6 A. Yeah, it depends on how you 7 count cohort studies. But those are 8 publications on the cohort studies. 9 Q. And so it's not that the 10 plaintiffs' experts don't consider the 11 cohort studies, they just think that on 12 balance they're not as reliable as -- 13 MR. TISI: What are you 14 shaking your head for? 15 MS. MILLER: Because 16 you're -- okay, I'll wait. I'll 17 object at the end. I didn't mean 18 to be shaking my head. 19 MR. TISI: You've been doing 20 it the whole time. 21 MS. MILLER: There's a video 22 that will -- 23 MR. TISI: It will. 24 BY MR. TISI:</p>
<p style="text-align: right;">Page 359</p> <p>1 address them and your opinions about them 2 are pretty clear. 3 A. So you're talking about the 4 paragraph that says, "The final argument 5 made by plaintiffs' experts"? 6 Q. Yeah. Actually and it 7 starts -- you talk about all of the -- 8 you address all of the issues that -- I 9 mean, this is not a trick question. 10 A. Yeah. 11 Q. You are addressing all of 12 the issues that the plaintiffs' experts 13 raise about the cohort studies here, and 14 you don't think that they're valid, and 15 you give the reasons for that, correct? 16 MS. MILLER: Objection. 17 Objection. 18 THE WITNESS: So yeah, you 19 know, as it says here, I -- I say 20 plaintiffs cite certain things, 21 and I point out why I disagree 22 with their methodology. 23 BY MR. TISI: 24 Q. Okay. In your opinion?</p>	<p style="text-align: right;">Page 361</p> <p>1 Q. So the question is not -- 2 your contention is not that the 3 plaintiffs' experts don't address the 4 cohort studies. You just disagree about 5 the interpretation that they give to the 6 cohort studies; is that fair? 7 MS. MILLER: Objection. 8 Objection. 9 THE WITNESS: My concern is 10 the methodology used by the 11 plaintiffs in doing their -- their 12 whole analyses of the data in 13 total. 14 BY MR. TISI: 15 Q. And what methodology do you 16 think that they used wrong with respect 17 to the cohort studies? 18 A. I -- well, again, I think 19 that they -- in terms of the methodology, 20 I was talking about methodology, sort of 21 in general. I don't think that they're 22 applying the Bradford Hill criteria in a 23 methodologically correct manner. 24 And so for the cohort</p>

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<p>1 studies, I point out, you know, what they 2 say as to why, you know, they say that, 3 well, the cohort studies, you know, 4 really have no play in terms of 5 determining consistency. 6 Q. Is that what you think they 7 say? 8 A. I'm paraphrasing. I do 9 not -- I do not see -- I don't know 10 offhand, and I'll have to read through 11 carefully. But it's I seem to remember 12 that none of the plaintiffs' experts said 13 that -- that they gave cohort studies 14 more weight than they did the 15 case-control studies. 16 Q. And you think that they 17 should have said cohort studies should be 18 given more weight than case-control 19 studies? 20 A. I'm -- 21 MS. MILLER: Objection. 22 THE WITNESS: I'm saying -- 23 MS. MILLER: Please give me 24 time to object. I know everybody</p>	<p>1 plaintiffs' experts, there's several of 2 them. There's misclassification bias 3 that they identified. You know what that 4 is, right? 5 A. Can you point in particular 6 where they identified a mis -- 7 Q. Well, I'm asking you. You 8 identified it in your report. You said 9 that one of the issues that were raised 10 was that they did not -- the issue that 11 Dr. Rothman raised -- 12 MS. MILLER: Do you want to 13 tell us what page you are reading? 14 MR. TISI: Page 28. 15 MS. MILLER: That would help 16 a lot. 17 MR. TISI: I'm on Page 28. 18 I told you before. 19 THE WITNESS: Yeah, yeah, 20 but I don't know from there where 21 you're reading. 22 BY MR. TISI: 23 Q. Okay. Let me ask you this. 24 Did they identify misclassification bias?</p>
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<p>1 is tired this afternoon. 2 BY MR. TISI: 3 Q. I mean, I'm reading what 4 you. You said, "I don't know offhand but 5 I'll have to read through carefully. But 6 it seemed -- I seem to remember that none 7 of plaintiffs' experts said that they 8 gave cohort studies more weight than they 9 did case-control studies." 10 And you think that's a 11 methodologic flaw? 12 A. I -- I -- in the end I may 13 be misremembering exactly what they said. 14 But I do believe some of them said I 15 weighted the case-control studies more 16 because here are flaws in the cohort 17 studies and that sort of makes them 18 invalid. 19 And due to the generally 20 accepted principle in epidemiology that 21 cohort studies have higher evidence than 22 do case-control studies, I don't think 23 that's correct. 24 Q. But the biases that the</p>	<p>1 A. I don't know. I mean, can 2 you -- 3 Q. I'm asking you. You're the 4 expert. I'm just a lawyer. Did they 5 identify misclassification bias? 6 A. I'll have to go through all 7 the expert reports and see which ones. 8 Q. I'm asking, in your 9 report -- in your report, do you identify 10 that she would -- that the witness's 11 plaintiff were concerned about 12 misclassification bias? 13 A. I'll have to go through my 14 report. 15 MR. LOCKE: Objection to 16 form. Maybe it's just the 17 pronouns. But are you talking 18 about a specific witness? 19 MR. TISI: No. She's 20 lumping them altogether. 21 MS. MILLER: Where is she 22 lumping them altogether? 23 BY MR. TISI: 24 Q. Plaintiffs' experts. It</p>

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<p>1 says the final argument made by 2 plaintiffs' experts. 3 A. Yes. And I cite two of 4 them, so what is 15 and 73? 5 So one is, as I -- we've 6 been talking about, is that the level of 7 evidence in cohort studies is weaker than 8 that in case-control studies. 9 And number 15 and 73 are -- 10 so that would be McTiernan and Moorman. 11 Q. Okay. So now let me ask you 12 this. Do the witnesses -- do as a whole, 13 do the plaintiffs' experts, one, or all 14 of them, talk about the issue of 15 misclassification bias? 16 MS. MILLER: Objection. 17 THE WITNESS: I can't 18 remember off the top of my head. 19 BY MR. TISI: 20 Q. But you know what 21 misclassification bias is, right? 22 A. Yes, I do. 23 Q. What is it? 24 A. It's when you put a case</p>	<p>1 THE WITNESS: That's more of 2 a feasibility question and a 3 resource question. I don't see 4 how that creates any biases or 5 confounding or issues like that. 6 BY MR. TISI: 7 Q. One of the things that you 8 raised is that Narod had mentioned that 9 there should be 200,000 patients. Do you 10 remember that? 11 A. Yes, I do. We can look at 12 it here. 13 Q. Let me ask you. Did you 14 ever -- did you -- did you do any power 15 calculation to determine how big a cohort 16 study would have to be in order to 17 identify a risk of ovarian cancer? 18 MR. LOCKE: Objection. 19 BY MR. TISI: 20 Q. If you disagree -- if you 21 disagree with Dr. Narod? 22 MS. MILLER: Objection. 23 Is the question the first 24 one or is the second question?</p>
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<p>1 into the control group or you put a 2 control into the case group. 3 Q. Okay. And that is a 4 recognized bias and that's what 5 Dr. Rothman was talking about -- is a 6 recognized bias within -- within cohort 7 studies, correct? 8 A. It doesn't have to be just 9 cohort studies you can have 10 misclassification biases in case-control 11 studies. 12 Q. Okay. But that is a 13 recognized concern about cohort studies, 14 right? 15 A. It's something one needs to 16 be aware of when they are looking at 17 cohort studies. It doesn't mean that 18 every cohort study has misclassification 19 bias. 20 Q. Isn't it also another 21 concern that the studies -- that cohort 22 studies are difficult to design if 23 they're studying a rare disease? 24 MS. MILLER: Objection.</p>	<p>1 Is, "Do you disagree with 2 Dr. Narod a question?" Or is it 3 editorial content? What is that? 4 Objection. 5 MR. TISI: Thank you. 6 That's -- that's all you have to 7 say. 8 MS. MILLER: Well, I need to 9 know. 10 MR. TISI: You don't. 11 MS. MILLER: The witness 12 needs to know. 13 MR. TISI: She's doing just 14 fine. 15 MS. MILLER: Do you know 16 what the question is? 17 THE WITNESS: I'm not sure. 18 BY MR. TISI: 19 Q. Doctor -- 20 A. But I heard that I -- 21 Q. Because you were queued by 22 your lawyer, let me ask you this -- 23 MS. MILLER: It doesn't take 24 a queue to know.</p>

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<p style="text-align: right;">Page 370</p> <p>1 BY MR. TISI: 2 Q. You recall -- you recall -- 3 MR. TISI: Counsel, please. 4 BY MR. TISI: 5 Q. You recall that you -- that 6 Dr. Narod said that you would have to 7 have 200,000 patients in a cohort study 8 in order to detect -- detect ovarian 9 cancer, do you remember that? 10 A. We can go to the Narod 11 study. I just want to make sure exactly 12 what he said, but... 13 MS. MILLER: Is there a 14 specific part of her report that 15 you're referring to? 16 MR. TISI: I'll find it for 17 you. Honestly, she remembers it, 18 so you don't have to keep doing 19 that. 20 BY MR. TISI: 21 Q. Do you see in the middle of 22 Page 26 where it says, on your report, 23 "Across two different prospective 24 studies, there were approximately 1,400</p>	<p style="text-align: right;">Page 372</p> <p>1 A. I'm saying on the basis of 2 what we have here, I mean, if you read 3 that whole thing, it says, "Across the 4 three prospective studies there's 1,400 5 women with ovarian cancer, over 200,000 6 without." So if you take those numbers, 7 the power to detect a hazard ratio of 1.2 8 or larger is over 90 percent with a 9 two-sided level of significance of .05. 10 Q. Do you know whether or not 11 other people outside of litigation have 12 actually looked at the concerns about the 13 cohort studies that the plaintiffs' 14 experts have identified? 15 A. I'm not sure what the 16 question is. 17 Q. Well, I'll read it again. 18 A. I mean, is there a 19 publication that looked at the cohort -- 20 Q. Do you know whether or not 21 people -- people, scientists outside of 22 litigation, have looked at the issues 23 related to the talc cohort studies and 24 agreed with the plaintiffs?</p>
<p style="text-align: right;">Page 371</p> <p>1 women diagnosed with ovarian cancer and 2 more than 200,000 women who were not 3 diagnosed with ovarian cancer." 4 Do you see that? 5 A. Yes. I see that. 6 Q. Okay. So now my question 7 is, did you do any power calculations to 8 determine how big the cohort studies 9 would have to be to detect ovarian 10 cancer, or are you relying on Narod? 11 A. I think if you go down. It 12 says the power to detect a hazard ratio 13 of 1.2 or larger is over 90 percent with 14 a two-sided level of confidence of 0.05. 15 Clearly this is sufficient power for an 16 association of 1.26 that is observed in 17 the case-control studies to be found 18 statistically significant. 19 So that -- so that is a 20 power statement. 21 Q. Okay. I'm asking you how 22 many patients would have to be enrolled 23 in a study. So what would that turn out 24 to be?</p>	<p style="text-align: right;">Page 373</p> <p>1 MS. MILLER: Objection. 2 THE WITNESS: I'm -- I mean, 3 the meta-analyses obviously looked 4 at the cohort studies, and I do 5 not remember -- 6 BY MR. TISI: 7 Q. Did you read the Taher? 8 A. The unpublished study that 9 hasn't been through peer review yet? 10 Q. Actually -- it's actually 11 been through peer review. But it's not 12 been published yet. You're correct. 13 But let me ask you -- 14 A. So there's a notification of 15 publication? 16 Q. Doctor, just I'm not 17 under -- I'm not under oath here. 18 A. Sorry. 19 Q. I'm asking you -- I'm asking 20 you this question? 21 A. Yeah. 22 MR. TISI: Are we laughing? 23 Is that part of -- part of 24 deposition protocol?</p>

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<p>1 MS. SHARKO: Well, you 2 represented that it was 3 peer-reviewed. 4 MR. TISI: I'm 5 representing -- 6 MS. SHARKO: And then you say 7 you're not under oath. Can we see 8 the peer review? Are you guys 9 part of that? 10 BY MR. TISI: 11 Q. Doctor -- Doctor -- 12 MR. TISI: I'm not part of 13 it, Counsel. You know I'm not 14 part of it. 15 MS. SHARKO: No, I don't. 16 BY MR. TISI: 17 Q. Do you know whether or not 18 the Taher authors have identified the 19 same weaknesses with the cohort study as 20 the plaintiffs' experts did? 21 A. I don't remember off the top 22 of my head -- 23 Q. Let's look at it. 24 A. -- but I would have sort of</p>	<p>1 was no question pending, Counsel. 2 BY MR. TISI: 3 Q. Okay. If you go to Page 43. 4 It says at the top, Although the reasons 5 are unclear, the difference potentially 6 due to issues related to latency, study 7 power or exposure misclassification. 8 And they're talking about 9 the difference between cohort and case 10 controls. 11 Do you see that? 12 A. I'm sorry, where were you 13 reading again? Was it starting 14 "although"? 15 Q. And the very top, "The 16 effect estimates of the meta-analysis 17 reported on 24-case-control studies" -- 18 A. Yes. 19 Q. -- "and three cohort studies 20 and refer to ever versus never use of 21 perineal talc. And it talks about the 22 fact that there's a difference between 23 the case-control and the cohort studies. 24 Do you see that?</p>
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<p>1 the same... 2 MR. TISI: Yes, hers has the 3 tab. 4 MS. MILLER: Do you want 5 this tab? 6 BY MR. TISI: 7 Q. You read the -- you read 8 the -- 9 MR. TISI: Yes, I did that 10 to make her life easy. 11 (Document marked for 12 identification as Exhibit 13 Ballman-22.) 14 THE WITNESS: So this looks 15 like a draft. 16 BY MR. TISI: 17 Q. Yes, correct. 18 A. So whether it's been 19 peer-reviewed. 20 Q. I'm asking you -- I'm asking 21 you whether they identified -- 22 MS. MILLER: You just 23 interrupted her. 24 MR. TISI: Okay. I -- there</p>	<p>1 A. Yes, I do. 2 Q. Okay. And "Although the 3 reasons for this are unclear, the 4 difference could potentially be due to 5 issues related to latency, study power or 6 exposure misclassification," correct? 7 A. You know, that's what he 8 says there. And I think it's really 9 striking that he doesn't talk about what 10 most people talk about in terms of the 11 limitations of the case-control studies. 12 So most people would say well, the reason 13 is, is because there's recall bias. And 14 we do have evidence of how recall bias 15 can affect these results from 16 Schildkraut. And so -- and so there it 17 can be kicked around -- 18 Q. There's no question -- 19 there's no question pending. 20 A. Well, you asked me -- 21 Q. I didn't ask you. I asked 22 you whether I read that right. 23 MS. MILLER: Please stop 24 interrupting her.</p>

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<p>1 MR. TISI: I asked you --</p> <p>2 MS. MILLER: She wants to</p> <p>3 give full, accurate answers.</p> <p>4 MR. TISI: But there was no</p> <p>5 question pending.</p> <p>6 MS. MILLER: And you're</p> <p>7 trying to stonewall her.</p> <p>8 MR. TISI: No, she's trying</p> <p>9 to stonewall me.</p> <p>10 BY MR. TISI:</p> <p>11 Q. I'm asking you this. I said</p> <p>12 their reason they identify three reasons</p> <p>13 why there could be a difference between</p> <p>14 the case-control and the cohort studies,</p> <p>15 did they not? And the answer is either a</p> <p>16 yes or no.</p> <p>17 MS. MILLER: Sometimes in</p> <p>18 life an answer isn't yes or no.</p> <p>19 And if the witness feels like she</p> <p>20 needs to give a complete answer,</p> <p>21 please allow her to give a</p> <p>22 complete answer.</p> <p>23 BY MR. TISI:</p> <p>24 Q. Doctor, did I read the</p>	<p>1 addressed in this paper?</p> <p>2 A. I don't know.</p> <p>3 Q. Okay.</p> <p>4 A. And let me just point --</p> <p>5 Q. So now, let's talk about the</p> <p>6 cohort studies, which is what we were</p> <p>7 talking about.</p> <p>8 MS. MILLER: She was in the</p> <p>9 middle of a sentence.</p> <p>10 BY MR. TISI:</p> <p>11 Q. The next paragraph talks</p> <p>12 about latency. It says, "Although cohort</p> <p>13 designs are efficient in examining</p> <p>14 diseases with long latency periods, it is</p> <p>15 essential that the period between talc</p> <p>16 exposures and cancer's diagnosis be</p> <p>17 specific" -- "sufficiently long.</p> <p>18 Gonzales suggested that the latency</p> <p>19 period for ovarian cancer is between 15</p> <p>20 and 20 years.</p> <p>21 "In the cohort studies</p> <p>22 included in this review, Houghton</p> <p>23 reported a mean follow-up of 12.4 years</p> <p>24 while Gates followed a cohort of women</p>
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<p>1 following statement correct:</p> <p>2 "Although the reasons for</p> <p>3 this are unclear, the difference could</p> <p>4 potentially be due to issues related to</p> <p>5 latency, study power, or study</p> <p>6 misclassification."</p> <p>7 A. You read that sentence</p> <p>8 correct. But you were saying that --</p> <p>9 that there are experts outside of</p> <p>10 litigation that have the same objections</p> <p>11 as do the plaintiffs' experts. And so I</p> <p>12 was -- and you're citing this.</p> <p>13 Q. Okay.</p> <p>14 A. And I'm trying to be</p> <p>15 completely, you know, truthful. And I'm</p> <p>16 saying this is surprising to me, because</p> <p>17 first of all, it hasn't been put through</p> <p>18 peer review. So I don't know if this</p> <p>19 will stand. The reviewers may say --</p> <p>20 well, you can say this the other way,</p> <p>21 which most people would, is the issue is,</p> <p>22 is that the case-control studies have</p> <p>23 recall bias and selection bias.</p> <p>24 Q. Have those not been</p>	<p>1 for 24 years. Gertig and Gonzales</p> <p>2 noticed that" -- "noted that one of their</p> <p>3 studies' main limitations one was the</p> <p>4 relatively short follow-up period that</p> <p>5 may not accurately detect a potential</p> <p>6 association between talc exposure and</p> <p>7 ovarian cancer."</p> <p>8 Do you see that?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: I do see that.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Okay. And that is the very</p> <p>13 same thing that the plaintiffs' experts</p> <p>14 identify, correct?</p> <p>15 MS. MILLER: Objection.</p> <p>16 BY MR. TISI:</p> <p>17 Q. You disagree with it, but</p> <p>18 they identified it?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: And I'm saying</p> <p>21 that the methodology and -- and</p> <p>22 sort of what's being stated here</p> <p>23 is -- is not a true representation</p> <p>24 of what's going on.</p>

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<p style="text-align: right;">Page 382</p> <p>1 BY MR. TISI: 2 Q. Okay. So they're wrong? 3 MS. MILLER: Objection. 4 THE WITNESS: I'm saying 5 that I -- I think that the 6 methodology applied has not -- has 7 some flaws in it. 8 BY MR. TISI: 9 Q. Okay. So the methodology of 10 these folks outside of litigation are 11 wrong -- 12 A. But these -- 13 Q. -- but yours is right? 14 A. Sorry. 15 Q. Correct? 16 MS. MILLER: Objection. 17 THE WITNESS: I'm saying 18 that I followed the general 19 principles of evaluating causation 20 on the basis of epidemiology good 21 practice. 22 And this has not even been 23 peer-reviewed yet, so... 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 384</p> <p>1 something outside of litigation that 2 hasn't been published to say, look, this 3 is in support of our experts' opinion. 4 So I don't know how that has much weight. 5 Q. The next statement is -- 6 deals with the power issue. In addition 7 cohort studies included -- may have 8 underpowered -- may have been 9 underpowered to detect an odds ratio of 10 1.3 from the case-control studies. This 11 was noted by Narod who suggested a cohort 12 of at least 200,000 women would be needed 13 to reach statistical significance if the 14 true odds ratio is 1.3. The cohort 15 studies included in this review included 16 much smaller cohort studies, ranging 17 between 41,000 and 78,000 women. 18 Do you see that? 19 A. I see where it's stated 20 there. 21 MS. MILLER: You didn't read 22 that exactly. 23 MR. TISI: I didn't read it 24 exactly. You're right.</p>
<p style="text-align: right;">Page 383</p> <p>1 Q. So the next -- nor has your 2 report, right? 3 MS. MILLER: Objection. 4 BY MR. TISI: 5 Q. Your report hasn't been 6 peer-reviewed, right? 7 MS. MILLER: Objection. 8 THE WITNESS: So I'm not 9 using anything outside of 10 litigation that hasn't been 11 peer-reviewed to say, look, you 12 know, this -- 13 BY MR. TISI: 14 Q. But your -- 15 A. -- is in support of that. 16 And so that's -- 17 Q. But your report -- 18 A. -- what I'm saying. 19 Q. -- has not been 20 peer-reviewed, correct? 21 A. But that wasn't the relevant 22 thing. 23 Q. Okay. 24 A. You were pointing to</p>	<p style="text-align: right;">Page 385</p> <p>1 MS. MILLER: No, you didn't. 2 BY MR. TISI: 3 Q. My question is -- 4 MS. MILLER: So -- 5 BY MR. TISI: 6 Q. -- were any -- were any of 7 the cohort studies above 80,000 women? 8 A. I'm saying that if you look 9 at the meta-analyses of the cohort 10 studies, there -- it meets, as I said in 11 my report, meets the 200,000, and there 12 is sufficient power there. And The 13 meta-analyses of the cohort studies did 14 not find a statistically significant 15 result. 16 Q. Where was the meta-analysis 17 for the cohort studies? Where was that? 18 A. Oh, let's look at -- I think 19 Berge has meta-analysis of the cohort. 20 Penninkilampi also has a meta-analysis. 21 Those are the two most recent ones. And 22 those are published. 23 Q. The next -- the next thing 24 deals with the misclassification bias.</p>

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<p>1 MR. TISI: God bless you.</p> <p>2 BY MR. TISI:</p> <p>3 Q. On the next page, it says,</p> <p>4 Finally, in cohort studies talc exposure</p> <p>5 was assessed at cohort entry and was used</p> <p>6 to measure -- as a measure of chronic</p> <p>7 talc use during follow-up.</p> <p>8 It is possible women who</p> <p>9 were not exposed to perineal talc at the</p> <p>10 time of cohort entry began using talc</p> <p>11 later time and vice versa, possibly</p> <p>12 introducing nondifferential</p> <p>13 misclassification of exposure, which</p> <p>14 could have biased the risk estimate</p> <p>15 towards the null value of unity.</p> <p>16 MS. MILLER: I just want to</p> <p>17 say object. That was paraphrased.</p> <p>18 It wasn't read exactly.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Do you read that?</p> <p>21 A. I see where you're reading</p> <p>22 from.</p> <p>23 Q. And that's the same</p> <p>24 misclassification bias that Dr. Rothman</p>	<p>1 sort of take a deeper dive and see if</p> <p>2 there's any evidence for or against that.</p> <p>3 Q. Let's talk about strength of</p> <p>4 association.</p> <p>5 You -- I'm going to do this</p> <p>6 pretty quickly I think. On Page 22 of</p> <p>7 your report you talk about that, correct?</p> <p>8 A. I have a section that says</p> <p>9 strength of association.</p> <p>10 Q. And the first two sentences,</p> <p>11 you say, "The criterion does not have a</p> <p>12 hard threshold. There is no cut-off</p> <p>13 value for the magnitude of an association</p> <p>14 between an exposure required for a</p> <p>15 relationship to be causal."</p> <p>16 And you agree with that,</p> <p>17 correct?</p> <p>18 A. There's no hard threshold.</p> <p>19 I mean, there is no hard number that, you</p> <p>20 know, people would say, oh, it's 1.31.</p> <p>21 No, it's 1.32.</p> <p>22 Q. Okay. On Page 22, again,</p> <p>23 you say, "Most epidemiologists regard the</p> <p>24 relative risk odds ratio or risk ratios</p>
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<p>1 mentioned and plaintiffs' experts also --</p> <p>2 experts also mentioned as well.</p> <p>3 A. Yeah. And that's just a</p> <p>4 statement there, but it doesn't go into</p> <p>5 sort of how this applies to talc in</p> <p>6 general. It's just a general statement.</p> <p>7 So for instance, it doesn't</p> <p>8 acknowledge that most women begin talc</p> <p>9 use in their early adulthood. It doesn't</p> <p>10 acknowledge that -- so that means that</p> <p>11 most women by the time they're 55,</p> <p>12 probably wouldn't start using talc at</p> <p>13 that point.</p> <p>14 And even if they did, there</p> <p>15 probably wouldn't be sufficient follow-up</p> <p>16 time at that point for ovarian cancer to</p> <p>17 develop.</p> <p>18 So these are much more</p> <p>19 subtle than just sort of stating a</p> <p>20 platitude that, oh, yeah, this is a thing</p> <p>21 you have to look out for in cohort</p> <p>22 studies and, therefore, it's true.</p> <p>23 It is something that you</p> <p>24 have to look out for. But you have to</p>	<p>1 are less than 1.5 to be weak</p> <p>2 relationships."</p> <p>3 Do you see that?</p> <p>4 A. Yes. And I have citations</p> <p>5 there.</p> <p>6 Q. Okay. And then you go on to</p> <p>7 say, "Although there are instances where</p> <p>8 ratios under 1.5 are established to be</p> <p>9 causal based upon observational data,</p> <p>10 there are more instances where they are</p> <p>11 spurious due to confounding or bias."</p> <p>12 Do you see that?</p> <p>13 A. Yep. With the citation.</p> <p>14 Q. Okay. That citation is to</p> <p>15 an article by Taubes?</p> <p>16 A. Mm-hmm.</p> <p>17 Q. Okay. Who is Gary Taubes?</p> <p>18 A. I don't know offhand who he</p> <p>19 is.</p> <p>20 Q. Gary Taubes, is he a doctor?</p> <p>21 A. I -- I don't know offhand.</p> <p>22 If I could see the article. I could see</p> <p>23 if he has a Ph.D. or M.D. behind his</p> <p>24 name.</p>

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<p>1 MR. TISI: Exhibit 30, 2 please. 3 MS. MILLER: So that would 4 be 23. 5 MR. SOILEAU: Yes, that 6 would be 23. 7 MS. MILLER: I can't figure 8 out your code. But you're always 9 off by a always a different 10 number. 11 MR. TISI: Yes, it is, 12 because I'm off my -- 13 MS. MILLER: It's not like I 14 can even add or subtract. 15 (Document marked for 16 identification as Exhibit 17 Ballman-23.) 18 BY MR. TISI: 19 Q. I don't have the whole 20 thing. But I'm going to give you mine. 21 This is an article by Dr. Taubes. And it 22 has my highlighting on it, which of 23 course I will be glad to substitute one. 24 MS. SHARKO: We don't mind</p>	<p>1 really well respected journal. 2 Q. Do you know, Doctor, that 3 Taubes is a journalist and not a doctor? 4 A. Oh, I did not realize that. 5 But he's quoting many individuals in here 6 who are famous epidemiologists, Norman 7 Breslow. 8 Q. Doctor, do you see a nice, 9 big picture of -- 10 A. I see Ken Rothman in there. 11 Q. Yeah. 12 A. Who you say is -- so he -- 13 he may be reporting. But it's -- Sander 14 Greenland. 15 Q. That's the other guy who, if 16 you look at the book there, they both 17 co-authored the book on epidemiology? 18 A. Right. 19 Q. All right. And first of 20 all, is this a peer-reviewed article? 21 A. Since it says "Special news 22 report," I don't know if it was 23 peer-reviewed or not. 24 Q. Did you look and see whether</p>
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<p>1 your highlighting. 2 MR. TISI: That's okay. I'm 3 happy to have you show it to the 4 jury. 5 MS. MILLER: There's no jury 6 here. This is a Daubert 7 proceeding. We've established 8 that like 16 times. So I don't 9 know which jury you're talking 10 about. 11 MS. SHARKO: There's never 12 going to be a jury. We're going 13 to be done after Daubert. 14 MR. TISI: There have been 15 plenty of juries. They've all 16 said the same thing. 17 BY MR. TISI: 18 Q. Is that the article that 19 you've referred to? 20 A. Yes, it is. 21 Q. Okay. Can you tell me 22 whether Dr. Taubes -- first of all, it's 23 a news article, isn't it? 24 A. In -- in Science, which is a</p>	<p>1 or not the people who were quoted in this 2 news article, first of all, do you 3 typically cite news articles in your 4 published -- published papers? 5 MS. MILLER: Objection. 6 THE WITNESS: Well, if they 7 interview epidemiologists -- so 8 the epidemiologist interviewed by 9 Science, so I believe that 10 journalist would sort of report 11 correctly what the epidemiologist 12 said that they interviewed. 13 BY MR. TISI: 14 Q. So you don't -- you don't 15 buy fake news, huh? 16 MS. MILLER: Objection. 17 BY MR. TISI: 18 Q. Let me ask you this, Doctor. 19 MS. MILLER: Was that a 20 question that you actually want 21 her -- 22 MR. TISI: Yeah. I withdraw 23 it. I was making a joke, Counsel. 24 MS. MILLER: It's hard to</p>

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<p>1 tell. 2 BY MR. TISI: 3 Q. Did you see -- did you see 4 whether or not the people who were quoted 5 wrote a rebuttal to this report? 6 A. No, I did not look. 7 (Document marked for 8 identification as Exhibit 9 Ballman-24.) 10 BY MR. TISI: 11 Q. In the same article, and you 12 use the same rigor in doing -- in 13 drafting your report that you would do in 14 any publication, right? 15 MS. MILLER: Objection. 16 BY MR. TISI: 17 Q. In drafting your expert 18 report, you use the same scientific rigor 19 that would you use in every publication 20 that you -- that you'd use? 21 MS. MILLER: Objection. 22 THE WITNESS: I applied 23 scientific rigor in doing my 24 analyses and writing my report.</p>	<p>1 support your -- your statement, yes. 2 MS. MILLER: Objection. 3 That's -- 4 BY MR. TISI: 5 Q. The next sentence, he says, 6 A problem does -- A problem does not 7 exist with general medical reports about 8 single scientific studies. 9 Correct? 10 MS. MILLER: Objection. 11 MR. LOCKE: Objection. You 12 added a "not". 13 BY MR. TISI: 14 Q. "A problem does exist with 15 general media reports about single 16 scientific studies." 17 Correct? 18 A. Yes, that's what it says 19 there. 20 Q. And most of the examples 21 that are cited in the Taubes articles had 22 one observational study, correct? 23 A. Yeah. That might be the 24 case.</p>
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<p>1 BY MR. TISI: 2 Q. So in the same journal of 3 Science, Drs. -- if you look at the next 4 page, Drs. Willett, Greenland, MacMahon 5 Rothman, Thomas, Thun and Weiss wrote a 6 letter. 7 Do you see that? 8 A. Yes, I see that. 9 Q. Okay. And the first 10 sentence says, "In the special news 11 report, "Epidemiology Faces Its Limits," 12 Gary Taubes assembles a series of 13 quotations from ourselves and others 14 about potential methodologic pitfalls in 15 epidemiologic studies that might leave 16 readers with the misimpression that 17 evidence-based epidemiologic findings are 18 not usually credible." 19 Did I read that right? 20 A. Yeah, you read that right. 21 Does -- are we talking about -- is this 22 all in relation to threshold? 23 Q. This is all in relationship 24 to the study that you relied on to</p>	<p>1 Q. Okay. Now, talc has, we 2 established earlier, over 30, correct? 3 A. Well, again, it depends upon 4 how you measure studies. I don't know if 5 they are 30 independent with different 6 datasets. 7 Q. Certainly over one? 8 A. That's correct. 9 Q. Okay. It says, "Taubes 10 seems to perpetuate this confusion by 11 listing several media reports of 12 published findings and telling the 13 reader, 'You should be the judge.'" 14 Do you see that? 15 A. I see where you're reading 16 from. 17 Q. Okay. It goes on to say, 18 "In any scientific field, findings of 19 individual studies are not usually 20 considered seriously until confirmed by 21 others. Also, in epidemiology, as in 22 another scientific fields, more powerful 23 studies need to be conducted to evaluate 24 smaller fixed."</p>

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<p style="text-align: right;">Page 398</p> <p>1 Do you see that?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 THE WITNESS: Yep.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. So you cited the</p> <p>6 Taubes article but you didn't really</p> <p>7 consider the quotations, the</p> <p>8 epidemiologist who thought differently,</p> <p>9 correct?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: But I think</p> <p>12 there are other quotations, such</p> <p>13 as, "Often doing so will require</p> <p>14 large and long-term prospective</p> <p>15 studies."</p> <p>16 And it also states that,</p> <p>17 "Taubes writes that, I have</p> <p>18 expressed the view that a fourfold</p> <p>19 risk should be taken seriously.</p> <p>20 This is correct, but only when the</p> <p>21 finding stands in the biological</p> <p>22 vacuum" --</p> <p>23 BY MR. TISI:</p> <p>24 Q. Right.</p>	<p style="text-align: right;">Page 400</p> <p>1 Cancer Institute is?</p> <p>2 A. You mean what is it?</p> <p>3 Q. Yes.</p> <p>4 A. I thought you said who. Is</p> <p>5 it who or what?</p> <p>6 Q. What is the National Cancer</p> <p>7 Institute?</p> <p>8 A. So it's -- it's a government</p> <p>9 agency that funds cancer research.</p> <p>10 Q. Okay. Would it surprise you</p> <p>11 that the National Cancer Institute</p> <p>12 characterized risks as low as 1.2 as a</p> <p>13 moderate risk and not a weak risk?</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: Can I see what</p> <p>16 you're citing that from, please?</p> <p>17 MR. TISI: Sure.</p> <p>18 BY MR. TISI:</p> <p>19 Q. National Cancer Institute,</p> <p>20 PDQ on the NI -- from "Ovarian Fallopian</p> <p>21 Tube and Primary Peritoneal Cancer:</p> <p>22 Peritoneal Cancer Prevention."</p> <p>23 (Document marked for</p> <p>24 identification as Exhibit</p>
<p style="text-align: right;">Page 399</p> <p>1 A. -- "and has no" -- "or no</p> <p>2 biomedical credibility."</p> <p>3 Q. Okay.</p> <p>4 A. "We all take seriously small</p> <p>5 relative risk when there are credible</p> <p>6 hypothesis in the background."</p> <p>7 Q. And you don't think the</p> <p>8 hypothesis that talc could cause ovarian</p> <p>9 cancer is credible?</p> <p>10 A. After doing my complete</p> <p>11 scientific review, I -- I again come to</p> <p>12 the conclusion that there's no evidence</p> <p>13 of a causal relationship between</p> <p>14 peritoneal talcum powder exposure and</p> <p>15 ovarian cancer.</p> <p>16 Q. Okay. You mentioned that</p> <p>17 you think that the -- most</p> <p>18 epidemiologists would categorize the</p> <p>19 risks seen in these studies as weak?</p> <p>20 A. I -- yes.</p> <p>21 Q. Okay. Who is the National</p> <p>22 Cancer Institute?</p> <p>23 A. What is it?</p> <p>24 Q. Do you know who the National</p>	<p style="text-align: right;">Page 401</p> <p>1 Ballman-25.)</p> <p>2 BY MR. TISI:</p> <p>3 Q. Do you see that?</p> <p>4 A. Yes, I see that. That's the</p> <p>5 title of the article. Yes.</p> <p>6 Q. And if you go to Page 3. It</p> <p>7 identifies factors with adequate evidence</p> <p>8 of increased risk of ovarian, fallopian</p> <p>9 tube and primary peritoneal cancer.</p> <p>10 Do you see that?</p> <p>11 A. Yes, I do.</p> <p>12 Q. Okay. And it talks about</p> <p>13 for each one of them, the magnitude of</p> <p>14 the effect?</p> <p>15 A. Yes, I see that.</p> <p>16 Q. Okay. The magnitude of</p> <p>17 effect for endometriosis is modest with</p> <p>18 an observed relative risk rate of 1.8 to</p> <p>19 2.4?</p> <p>20 A. Yes.</p> <p>21 Q. Magnitude of the effect for</p> <p>22 hormone replacement therapy is modest</p> <p>23 with a relative risk of 1.2 to 1.8?</p> <p>24 A. Yes.</p>

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<p style="text-align: right;">Page 402</p> <p>1 Q. And obesity and height talks 2 about, "Based on fair evidence, obesity 3 and height are associated with a modest 4 increase of ovarian cancer," which they 5 describe down below as a 1.1. 6 A. Yes. I see that. 7 MS. MILLER: Can you -- 8 BY MR. TISI: 9 Q. Are there -- so would you -- 10 would you agree with me that at least in 11 this document, that there are people who 12 define magnitude of risk of 1.1 to 1.2 as 13 a modest risk? 14 MS. MILLER: Objection. Are 15 we talking about relative risks? 16 Or are we talking -- 17 MR. TISI: You can clarify, 18 Counsel. She's looking at it. 19 MS. MILLER: That's an 20 objectionable question. 21 MR. TISI: Of course. Every 22 one of my questions is. 23 MS. SHARKO: Exactly. 24 MS. MILLER: Fix that.</p>	<p style="text-align: right;">Page 404</p> <p>1 don't think talc is listed here. 2 Q. I understand. Counsel -- 3 counsel can ask you this question. This 4 is not your opportunity to pontificate. 5 MR. LOCKE: Objection. 6 MS. MILLER: Objection. 7 BY MR. TISI: 8 Q. Let's talk about consistency 9 and statistical significance now, because 10 this is a big part of your report. 11 Please pull out Exhibit 6, 12 which is the Bradford Hill article. 13 A. Yes, I have. 14 Q. On Page 8 it talks about 15 consistency. It says, "Next to my list." 16 A. Yes. 17 Q. Okay. It does not say 18 different designs, does it? Can you read 19 it for the record, please? 20 A. Yes. It says, "Has it been 21 repeatedly observed by different persons 22 in different places, circumstances, and 23 times?" 24 Q. Okay. It doesn't talk about</p>
<p style="text-align: right;">Page 403</p> <p>1 THE WITNESS: So this has 2 nothing to do with -- 3 MS. MILLER: You have the 4 power to change that. 5 MR. TISI: Every one of my 6 questions is. You've made that 7 clear. 8 THE WITNESS: This has 9 nothing to do with trying to 10 identify what the strength of an 11 association is within the context 12 of a Bradford Hill. 13 BY MR. TISI: 14 Q. So is the Bradford -- 15 A. This is more, I think, for 16 lay people. I mean, it says, "Who's at 17 risk?" I don't think this is for 18 scientists. 19 And so, you know, so I don't 20 know what their reference basis is. And 21 I note that -- 22 Q. I have -- no question is 23 pending. 24 A. Let me go through, but I</p>	<p style="text-align: right;">Page 405</p> <p>1 study design, does it? 2 A. I don't know. Circumstances 3 could fall under -- I mean, study design 4 could fall under circumstances. 5 Q. It doesn't say anything 6 about statistical significance, does it? 7 A. You know, I read -- where 8 did I read -- 9 So it's going to take me a 10 while to go through where he talks 11 about -- yeah, so the lesson here is 12 that, "Broadly the same answer has been 13 reached in quite a wide variety of 14 situations and techniques." 15 So I would consider study 16 design a technique. In other words, it's 17 not due to some constant error or fallacy 18 that permeates every inquiry. 19 Q. Okay. So now the next thing 20 if I go to Page 17 of your report under 21 consistency, the second sentence. 22 A. Under consistency. 23 Q. Right. It says -- I'll read 24 it into the record. "Results across</p>

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<p>1 studies are consistent if the risk ratios 2 are numerically close to one another and 3 the results are statistically significant 4 in most studies." 5 A. Yes. 6 Q. Let's take each part. 7 Numerically close to one another. First 8 of all, there's no citation to that 9 whatsoever, is there? 10 A. Again, I mean, it's like 11 what does consistency mean. Well, I 12 mean, it means that you have numbers that 13 are close to each other. A number 14 wouldn't be consistent if one is one and 15 another is 100. I think that's common 16 sense. 17 Q. Okay. Well -- okay. 18 A. And as well as, you know, 19 results are statistically significant in 20 most studies. Again, I think that's how 21 most people -- most epidemiologists would 22 interpret consistency. 23 Q. Well, on Page 26 of the 24 report, if you go there, you criticize</p>	<p>1 asking you one question at a time, 2 Doctor. 3 A. I don't think it's a yes or 4 no answer. 5 Q. Are you not criticizing 6 them -- "Unfortunately, they do not 7 indicate what is meant by relative 8 stability. They did not provide a 9 definition." 10 Do you see that? 11 A. I did not say that they did 12 not provide a cross -- 13 Q. You say, "Unfortunately, 14 they do not indicate what is meant by 15 relative stability." 16 A. Right. I did not say 17 definition. 18 Q. Okay. Do you indicate what 19 you mean by numerically close to one 20 another -- 21 A. So -- 22 Q. -- on Page 17? 23 MS. MILLER: Objection. 24 THE WITNESS: I -- I --</p>
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<p>1 the plaintiffs' experts in another 2 context. You say, "Arguments have been 3 made by plaintiffs' experts that the 4 results are consistent. Some experts 5 emphasize what they see is a relative 6 stability of the estimates across time, 7 diverse population, and across diverse 8 study designs. Unfortunately, they do 9 not indicate what is meant by relative 10 stability." 11 Do you see that? 12 A. I'm sorry, no. I haven't 13 gotten there. 14 Q. It's the last paragraph. 15 A. Yes. I see that. 16 Q. And you're critical of the 17 plaintiffs' experts for in the defining 18 the terms, right? 19 A. But if you go on -- 20 Q. I'm asking you a question. 21 You're critical of plaintiffs' experts 22 for not defining their terms, correct? 23 A. Can I finish? 24 Q. No, I'm asking you -- I'm</p>	<p>1 that's where I was going. It's 2 transfer -- I do have sort of 3 criteria -- where was it, Page 17? 4 So when I apply the 5 criteria, I say how I apply it. 6 And so I'm trying to look for that 7 right now. 8 BY MR. TISI: 9 Q. No, I'm asking you the 10 general principles, Doctor. What is -- 11 how do you define numerically close? 12 What is your definition and your 13 authority for that? 14 A. Common sense. And I'm going 15 to where I applied it, as the plaintiffs 16 did not give this a definition in their 17 sort of how to do consistency and their 18 general setup of consistency, what I'm 19 saying is when they reported their 20 results on consistency, they just make a 21 statement that it's relatively stable, 22 but they don't even give an indication of 23 what they mean by relatively stable. 24 Q. And you don't think the --</p>

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<p style="text-align: right;">Page 410</p> <p>1 A. So in my --</p> <p>2 MS. MILLER: She's still</p> <p>3 talking.</p> <p>4 THE WITNESS: In my general</p> <p>5 setup, I do not indicate. But I</p> <p>6 do when I go through sort of the</p> <p>7 consistency evaluation, I do give</p> <p>8 magnitudes of the ranges that were</p> <p>9 reported in the case-control</p> <p>10 studies that are almost fourfold</p> <p>11 different.</p> <p>12 BY MR. TISI:</p> <p>13 Q. I understand.</p> <p>14 A. Versus -- well, that's</p> <p>15 what -- you asked me about consistency.</p> <p>16 Q. No. But I'm asking you</p> <p>17 where you -- no, but I'm asking --</p> <p>18 A. And that's how I --</p> <p>19 Q. You're not answering my</p> <p>20 question.</p> <p>21 MS. MILLER: Stop talking</p> <p>22 over each other. Let her finish</p> <p>23 her sentence.</p> <p>24 BY MR. TISI:</p>	<p style="text-align: right;">Page 412</p> <p>1 THE WITNESS: -- the</p> <p>2 analysis -- I'm answering.</p> <p>3 BY MR. TISI:</p> <p>4 Q. You are not --</p> <p>5 MS. MILLER: Let her finish</p> <p>6 her sentence.</p> <p>7 BY MR. TISI:</p> <p>8 Q. You are not answering my</p> <p>9 question with all due respect.</p> <p>10 MS. SHARKO: You haven't</p> <p>11 heard her whole answer.</p> <p>12 MR. TISI: This is --</p> <p>13 MS. MILLER: Maybe -- maybe</p> <p>14 she was about to give you the</p> <p>15 answer you wanted.</p> <p>16 MR. TISI: This is --</p> <p>17 MS. MILLER: You have to let</p> <p>18 her finish talking.</p> <p>19 BY MR. TISI:</p> <p>20 Q. This is -- you provide --</p> <p>21 MS. MILLER: You don't let</p> <p>22 me talk either.</p> <p>23 BY MR. TISI:</p> <p>24 Q. You provide a statement,</p>
<p style="text-align: right;">Page 411</p> <p>1 Q. You are really not answering</p> <p>2 my question.</p> <p>3 Doctor, with all due</p> <p>4 respect, and I -- because I think it's</p> <p>5 important here. I want to know what your</p> <p>6 definition is of numerically close, and I</p> <p>7 want to know where you get it from.</p> <p>8 A. So I think this is a bit</p> <p>9 unfair. You're asking me for a</p> <p>10 definition of numerically close. And</p> <p>11 when I just sort of give a general</p> <p>12 gestalt of what's meant by consistency.</p> <p>13 And then you're saying but</p> <p>14 you criticize the other plaintiffs'</p> <p>15 experts because they don't say what</p> <p>16 relatively stable is. And their</p> <p>17 statements are in terms of when they</p> <p>18 looked at consistency, not a definition</p> <p>19 of consistency.</p> <p>20 So I'm saying let's look and</p> <p>21 I'll show you why I say they're not</p> <p>22 consistent. And when I invoke --</p> <p>23 Q. But you're not answering.</p> <p>24 MS. MILLER: Let her finish.</p>	<p style="text-align: right;">Page 413</p> <p>1 okay, here about consistency. This is in</p> <p>2 your general section, 5.1.2, correct?</p> <p>3 Without regard to talc.</p> <p>4 A. I -- I say -- I provide a</p> <p>5 general statement there.</p> <p>6 Q. Okay. And your general</p> <p>7 statement is that numerically close --</p> <p>8 A. Yes.</p> <p>9 Q. Okay. You use numerically</p> <p>10 close. And I want to know where -- other</p> <p>11 than you said common sense and gestalt,</p> <p>12 okay, those are your two things, kind of</p> <p>13 like the sniff test that you used in</p> <p>14 Viagra, right?</p> <p>15 MR. LOCKE: Objection.</p> <p>16 BY MR. TISI:</p> <p>17 Q. I want to know where your --</p> <p>18 where your --</p> <p>19 MS. MILLER: He wasn't done</p> <p>20 with the question. I was going to</p> <p>21 object. Don't worry.</p> <p>22 BY MR. TISI:</p> <p>23 Q. Okay. Then let me back up.</p> <p>24 You remember the sniff test that you used</p>

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<p style="text-align: right;">Page 414</p> <p>1 in Viagra, right?</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: I don't</p> <p>4 remember exactly how I used it. I</p> <p>5 do remember using those terms.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Right. So this is the</p> <p>8 gestalt test or the common sense test</p> <p>9 that you used.</p> <p>10 MS. MILLER: Objection.</p> <p>11 BY MR. TISI:</p> <p>12 Q. I want to know exactly where</p> <p>13 you get your cut-off for what is</p> <p>14 numerically close for the consistency</p> <p>15 prong of Bradford Hill?</p> <p>16 MR. LOCKE: Objection.</p> <p>17 THE WITNESS: You know what,</p> <p>18 again, it all depends upon the</p> <p>19 situation. And that's why there's</p> <p>20 no solid number within the</p> <p>21 definition for the general thing.</p> <p>22 You also then brought up --</p> <p>23 and that's what I'm trying to get</p> <p>24 the whole truth out there, is I</p>	<p style="text-align: right;">Page 416</p> <p>1 conclusion, versus the plaintiffs'</p> <p>2 experts, which just say they're</p> <p>3 relatively stable.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. Let me do the next</p> <p>6 one. Last paragraph in the consistency</p> <p>7 section, last -- I'm going to read it</p> <p>8 into the record. It's the first</p> <p>9 paragraph.</p> <p>10 "However" --</p> <p>11 MS. MILLER: You said last</p> <p>12 paragraph. Then you said first</p> <p>13 paragraph.</p> <p>14 BY MR. TISI:</p> <p>15 Q. First paragraph, last couple</p> <p>16 sentences.</p> <p>17 Tell me where you are. Are</p> <p>18 you with me, Doctor? Right here.</p> <p>19 Consistency. Page 17.</p> <p>20 A. No, I was on 24. Yes.</p> <p>21 Q. Okay. You say -- I'll read</p> <p>22 it into the record. "However, if</p> <p>23 adequately powered studies do not achieve</p> <p>24 statistical significance, this is</p>
<p style="text-align: right;">Page 415</p> <p>1 criticize the plaintiffs' experts</p> <p>2 by saying relatively stable</p> <p>3 without giving any sort of</p> <p>4 indication.</p> <p>5 But their relatively stable</p> <p>6 was just in their conclusion that</p> <p>7 they're consistent, whereas when I</p> <p>8 look at the consistency analyses,</p> <p>9 I give more numbers and ranges as</p> <p>10 to why I believe those numbers are</p> <p>11 not consistent.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Right. But that's your</p> <p>14 opinion. You don't give any basis for</p> <p>15 it. You don't give any citation. You</p> <p>16 don't give any published peer-reviewed</p> <p>17 literature which would -- against which</p> <p>18 we could measure your opinion, do you?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: There wouldn't</p> <p>21 be any published peer-reviewed</p> <p>22 literature that would say that.</p> <p>23 But I am -- I'm giving my criteria</p> <p>24 and metrics and how I came to my</p>	<p style="text-align: right;">Page 417</p> <p>1 evidence of inconsistency."</p> <p>2 Do you stand by that</p> <p>3 statement, first of all?</p> <p>4 A. However if adequately</p> <p>5 powered studies do not achieve</p> <p>6 statistical significance... Yes.</p> <p>7 Q. Okay. Next thing. "Another</p> <p>8 way an inconsistency can rise is if</p> <p>9 95 percent confidence intervals for the</p> <p>10 risk ratio estimates have no to little</p> <p>11 overlap with one another for adequately</p> <p>12 powered studies. If one study has a</p> <p>13 statistically significant result and the</p> <p>14 other does not, it means that the</p> <p>15 magnitude of the relative risk differs</p> <p>16 considerably, which is an inconsistency</p> <p>17 between the size of the estimated risk.</p> <p>18 Do you see that?</p> <p>19 A. I do see that.</p> <p>20 Q. Okay. Can you tell me</p> <p>21 what -- how you define no to little</p> <p>22 overlap? What's the -- what's the</p> <p>23 criteria for that and where do you get it</p> <p>24 from?</p>

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<p>1 First of all, there's no 2 citation for any of this, is there? 3 MS. MILLER: Objection. 4 First of all, so what is -- 5 MR. TISI: I was -- 6 MS. MILLER: You can't ask a 7 question that way. 8 MR. TISI: Counsel, I said 9 first of all, there is -- 10 MS. MILLER: Is the first 11 question stricken? 12 MR. TISI: Yes. 13 MS. MILLER: Okay. 14 BY MR. TISI: 15 Q. First of all, in the second 16 part of the paragraph you do not provide 17 a single citation, correct? 18 A. I do not provide a citation 19 there. 20 Q. Okay. Secondly -- okay, can 21 you tell me what you mean by no to little 22 overlap? What is the criteria and where 23 do you get it from? 24 A. That's was what I was trying</p>	<p>1 2016 and again just this week have 2 indicated that statistical significance 3 should not even be -- should not even be 4 mentioned when we are talking about 5 analyses like these, true? 6 MR. LOCKE: Objection. 7 MS. MILLER: Objection. 8 THE WITNESS: I have no idea 9 what it's referring to. But let 10 me -- let me sort of explain to 11 you the relationship between 12 statistical significance and 13 confidence intervals. 14 If one has a confidence 15 interval, one can infer whether or 16 not a result is statistically 17 significant at a certain level. 18 So one can sort of infer if 19 the P-value is going to be less 20 than or greater than .05 if you're 21 using a 95 percent confidence 22 interval. 23 So the reason they're saying 24 this, and I tell this people all</p>
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<p>1 to answer. I'm trying to see if I have 2 that citation here. And if I don't, I 3 can provide a citation. No, I don't 4 provide a citation there. But in the 5 literature, there are articles that state 6 how much -- in fact, confidence intervals 7 can overlap and the results still are 8 statistically significantly different. 9 Q. In fact, Doctor -- and we're 10 going to talk about this. Aren't you 11 aware that even this week, the American 12 Statistical Association published a 13 whole -- a whole volume of 43 articles 14 with an editorial recommending that they 15 get rid of the issue of statistical 16 significance and look at confidence 17 intervals? 18 A. Well, that's what I'm citing 19 there, that one can look at confidence 20 intervals and see if they overlap or not. 21 Q. Perfect. And we're going to 22 talk about that. Okay? 23 But you do understand that 24 the American Statistical Association in</p>	<p>1 the time when I teach, I never 2 just want to see a P-value, I want 3 the magnitude of the difference. 4 I want to know what is the 5 size of the difference and a 6 confidence interval on that, and I 7 would agree. I don't need the 8 P-value. 9 BY MR. TISI: 10 Q. And -- 11 A. And I could infer 12 statistical significance just based upon 13 the confidence interval. 14 So they are not saying don't 15 worry about statistical significance. 16 They are saying don't place so much 17 emphasis on the P-value itself. 18 Q. But also -- we're going to 19 talk about this for a moment. You would 20 agree that almost all of these studies 21 with a handful of exceptions, regardless 22 of study design, their confidence 23 intervals overlap at 1.2? 24 A. I have no idea.</p>

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<p>1 Q. We'll talk about that.</p> <p>2 MS. MILLER: Do you need a</p> <p>3 break?</p> <p>4 THE WITNESS: No, I'm good.</p> <p>5 BY MR. TISI:</p> <p>6 Q. On Page 26, you say the</p> <p>7 following with respect to the talc</p> <p>8 evidence: "There is clear</p> <p>9 inconsistency" -- Page 26?</p> <p>10 A. Yeah, I'm there. I'm not</p> <p>11 seeing where that statement -- or where</p> <p>12 that --</p> <p>13 Q. The last sentence of the</p> <p>14 paragraph in the middle?</p> <p>15 A. Okay. I'm with you.</p> <p>16 Q. There is clear inconsistency</p> <p>17 between different study types with</p> <p>18 case-control studies yielding a</p> <p>19 statistically significant association</p> <p>20 ranging from 1.26 to 1.35 and cohort</p> <p>21 studies yielding a nonstatistically</p> <p>22 significant association ranging from 1.02</p> <p>23 to 1.06, hence no evidence of a causal</p> <p>24 relationship because the results are</p>	<p>1 expert reports of any of the other</p> <p>2 defense experts in this case?</p> <p>3 A. Other defense experts?</p> <p>4 Q. Have you read Christian</p> <p>5 Merlo's?</p> <p>6 A. Yes, I have.</p> <p>7 Q. Did you have any problems</p> <p>8 with his report?</p> <p>9 A. Problems? What do you mean</p> <p>10 by problems.</p> <p>11 Q. Anything that you thought</p> <p>12 was wrong?</p> <p>13 A. I wasn't evaluating whether</p> <p>14 or not I agree or disagree with his</p> <p>15 report.</p> <p>16 Q. I'm going to show you a</p> <p>17 chart that he put in his report because</p> <p>18 you don't have one in yours. And I will</p> <p>19 stipulate that it is accurate to the</p> <p>20 extent that it is --</p> <p>21 A. Comes from his report?</p> <p>22 Q. I'm going to ask you to</p> <p>23 assume that it comes from his report and</p> <p>24 I'm going to use his numbers.</p>
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<p>1 inconsistent."</p> <p>2 Do you say that?</p> <p>3 A. I do.</p> <p>4 Q. Okay. And so you think that</p> <p>5 because these two sets of results are --</p> <p>6 one is statistically significant and one</p> <p>7 is not statistically significant, they</p> <p>8 are inconsistent?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: I'm saying</p> <p>11 that one set of results is</p> <p>12 establishing an association that's</p> <p>13 statistically significant. And</p> <p>14 I'm saying another one is saying</p> <p>15 there is no association because</p> <p>16 this is no statistical</p> <p>17 significance.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Okay. Now, you didn't put a</p> <p>20 Forest plot of the studies in your</p> <p>21 report, did you?</p> <p>22 A. I believe there is no Forest</p> <p>23 plot.</p> <p>24 Q. Okay. Have you reviewed the</p>	<p>1 MS. MILLER: I'll check my</p> <p>2 laptop to make sure that's true.</p> <p>3 (Document marked for</p> <p>4 identification as Exhibit</p> <p>5 Ballman-26.)</p> <p>6 BY MR. TISI:</p> <p>7 Q. Do you remember seeing this</p> <p>8 chart?</p> <p>9 A. I was expecting a Forest</p> <p>10 plot. Yes, I see this chart here. I've</p> <p>11 seen so many charts that if this comes</p> <p>12 from his study, yes, I believe --</p> <p>13 Q. And I'm using his because</p> <p>14 I'm sure the defense would object to me</p> <p>15 using anything else but their evidence.</p> <p>16 I'm using your evidence, and I'm putting</p> <p>17 it in front of you. Okay?</p> <p>18 MS. MILLER: Objection.</p> <p>19 BY MR. TISI:</p> <p>20 Q. And I'm asking you to assume</p> <p>21 it's true.</p> <p>22 MS. MILLER: If there's a</p> <p>23 statement there, I'm objecting.</p> <p>24 If there's a question there, I'm</p>

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<p>1 objecting. If there's a statement 2 there, I don't know what the point 3 of it was. 4 BY MR. TISI: 5 Q. There are 30 observational 6 studies here. And he identified them as 7 hospital-based case-control, 8 population-based case-controls, pooled 9 case-control studies, and cohort studies, 10 correct? 11 A. Yes, that's -- 12 MR. LOCKE: Objection. 13 Before you answer that question, I 14 don't have a copy of what you're 15 looking at. 16 MR. TISI: Oh, I'm sorry. 17 MS. MILLER: Wait. I'm 18 sorry. Did you just read us a 19 sentence? 20 THE WITNESS: No, he was -- 21 MR. TISI: They're 22 categorized. No, it's not. 23 They're categorized. One, 24 hospital based case-control</p>	<p>1 statistically -- statistical significance 2 issue, you would agree with me for the 3 hospital case-control studies with the 4 exception of the two Hartge papers, all 5 show a risk ratio greater than one? 6 A. The two Hartge pages? 7 Q. Yes. 8 A. Yes. That's what it's 9 showing here. 10 Q. Okay. You would also agree 11 with me that the population based 12 case-control studies, every single one of 13 them, whether they were statistically 14 significant or not, had a risk ratio of 15 greater than one. 16 MS. MILLER: Objection. 17 THE WITNESS: In this chart 18 that is true. 19 BY MR. TISI: 20 Q. Okay. The pooled 21 case-control study, Terry had a risk 22 ratio greater than one? 23 A. That's true. That's what 24 this --</p>
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<p>1 studies, population based 2 case-control studies -- 3 MS. MILLER: You talked so 4 fast, I thought you were reading 5 something that I didn't have. 6 I didn't realize you were -- 7 MR. TISI: I am reading it. 8 BY MR. TISI: 9 Q. Okay. There are four 10 categories of studies in this chart, 11 correct? 12 A. Yes, he lists four 13 categories of studies in the chart. 14 Q. And these four categories 15 are -- these studies are studies you 16 recognize, correct? 17 A. Yes. I recognize studies 18 that I reviewed. I don't know if they 19 are all there or if any extra or there. 20 But yes, in general. 21 Q. Okay. Now, would you agree 22 that irrespective of -- and I'm going to 23 put this aside for a minute. I'm going 24 to say it. Irrespective of the</p>	<p>1 Q. As was -- as is Cramer on 2 the next page? 3 A. Yes. 4 Q. And the cohort studies all 5 had risk ratios greater than one with the 6 exception of Gonzalez, correct? 7 A. Yes, that's correct. 8 Q. And would you agree with me, 9 risk ratio, the RR, is the same thing as 10 the point estimate, correct? 11 A. Yeah. Either it's an odds 12 ratio or it's a relative risk. But they 13 are point estimates. 14 Q. And the point estimate, just 15 for anybody going to read this, is the 16 most likely place where the risk resides? 17 A. It's more subtle than that. 18 Q. Okay. But just -- well, how 19 would you describe it? 20 A. I would say that what a 21 confidence interval shows, and this is 22 why people hate statistics, is that -- 23 (Brief telephone 24 interruption.)</p>

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<p style="text-align: right;">Page 430</p> <p>1 MS. SHARKO: That's someone 2 who loves statistics. 3 MR. TISI: Troy Rafferty was 4 calling to you. 5 MS. SHARKO: I'm happy to 6 talk with Troy. 7 THE WITNESS: Sorry. I was 8 trying to concentrate. 9 MS. MILLER: Yeah, that's 10 not fair to Dr. Ballman. Should 11 we -- the banter has confused her. 12 Should we go back and hear the 13 question again. 14 BY MR. TISI: 15 Q. Yeah. My question -- my 16 question is, what is your definition of a 17 point estimate. 18 Actually, let me -- let 19 me -- actually, that was not the 20 question. The question was, the point 21 estimate is the place within the 22 confidence interval that it's most likely 23 to be the true risk? 24 A. No, that's not correct.</p>	<p style="text-align: right;">Page 432</p> <p>1 before, Gonzalez, the -- cohort study, 2 and the two Hartge studies, that all of 3 the risk ratios here show a positive risk 4 ratio greater than one? 5 MS. MILLER: Objection. 6 THE WITNESS: As we 7 mentioned, most of the numbers 8 here are bigger than one. 9 BY MR. TISI: 10 Q. Okay. And that's what we 11 call a positive association, a positive 12 risk ratio? 13 MS. MILLER: Objection. 14 THE WITNESS: Well, I think 15 that -- 16 BY MR. TISI: 17 Q. Putting statistical 18 significance aside for a moment. I'll 19 talk about statistical significance. 20 A. Yeah, but I think it's 21 important. I think one would not say 22 there's a positive association if it's 23 not statistically significant. I mean, 24 it depends upon the context in which he</p>
<p style="text-align: right;">Page 431</p> <p>1 Q. Okay. Well, what is it? 2 A. So it's just the point 3 estimate that comes on based on the 4 actual data that you have on hand and 5 that you calculated. And it's for that 6 data. 7 And a confidence interval is 8 the interval such that if you would redo 9 the study with a different random set, 10 selected exactly the same way, many, many 11 times 95 percent of those intervals would 12 contain the real risk ratio. 13 Q. And is the number that is 14 reported, the risk ratio, more likely or 15 less likely than the number that's at the 16 tails? 17 A. I don't know how you would 18 measure that necessarily. Because you 19 have no idea what truth is. So you have 20 no idea within a given confidence 21 interval where the real estimate lies. 22 Q. But you would agree with me 23 that -- that all of these studies with 24 the exceptions that we talked about</p>	<p style="text-align: right;">Page 433</p> <p>1 was saying, so that might be misleading. 2 I mean, you know, a lot of people might 3 say, oh, they said there's a positive 4 association, and they would assume that 5 it was statistically significant. 6 Q. I understand. And we're 7 going to talk about statistical 8 significance in a moment. But I'm asking 9 you, all of these numbers with the 10 exception of the ones that I mentioned, 11 the two Houghton studies and the Gonzalez 12 cohort study, show a positive risk ratio? 13 MS. MILLER: Objection. 14 THE WITNESS: I mean, that's 15 one thing, yes, here in the study. 16 BY MR. TISI: 17 Q. Okay. 18 A. Risk ratios that are -- you 19 know, rated as weak, or no risk -- no 20 significant association. 21 Q. Okay. Now, I'm going to ask 22 you a hypothetical. If every one of 23 these studies was statistically 24 significant instead of some of them yes,</p>

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<p style="text-align: right;">Page 434</p> <p>1 some of them no, would you find 2 consistency? 3 MS. MILLER: Objection. 4 THE WITNESS: If every what? 5 BY MR. TISI: 6 Q. If every one -- 7 A. That that's not -- but 8 that's not the case. 9 Q. I understand. This is a 10 hypothetical. And I'm allowed to ask 11 hypotheticals. 12 If this chart were that 13 every one of these results were 14 statistically significant, would that -- 15 would those be consistent in your 16 opinion? 17 MS. MILLER: Objection. 18 THE WITNESS: Again, I mean, 19 I would have to look at the 20 ranges. They said it's just 21 magnitude. And then even 22 furthermore, you know, the next 23 step then would be consistent 24 what, and consistently biased,</p>	<p style="text-align: right;">Page 436</p> <p>1 that. I'm allowed to ask you 2 hypotheticals. 3 Okay. So my hypothetical is 4 that this chart -- this chart is exactly 5 as it is, except in the right-hand 6 column, there would be -- let's say -- 7 let's call them all weak associations. 8 Let's call them all weak but they would 9 all be statistically significant. 10 If that were to change, 11 would those, in your opinion, be 12 consistent? 13 MS. MILLER: Objection. 14 THE WITNESS: I think it 15 depends. And I think there 16 wouldn't be agreement in terms of 17 what the actual association is, 18 which would be quite weird. And 19 the fact that, you know, in 20 general, the cohort studies have 21 much lower estimates than do the 22 case-control studies. 23 BY MR. TISI: 24 Q. So is your answer they would</p>
<p style="text-align: right;">Page 435</p> <p>1 because these are all population 2 studies, and hence that's probably 3 why -- 4 BY MR. TISI: 5 Q. Well, no. There are cohort 6 studies in there. There's 7 hospital-based. If all of these studies, 8 regardless of design, was statistically 9 significant and the risk ratios were the 10 same, would they be consistent in your 11 opinion? 12 A. You know, again, I would 13 have to see what the actual numbers 14 were -- 15 Q. These are the numbers. 16 A. -- and so forth. 17 Q. These are the numbers. 18 A. But -- yeah, but you're 19 asking me to hypothesize something on 20 numbers that did not yield statistically 21 significant results. 22 Q. I understand. I'm 23 allowed -- I'm allowed to do that. I 24 really -- and your lawyers will tell you</p>	<p style="text-align: right;">Page 437</p> <p>1 be inconsistent? 2 A. I am saying it depends in 3 this hypothetical situation. I mean, I 4 would have to look at it more carefully 5 and do an analysis to see -- 6 Q. Would you -- 7 A. -- because that wasn't the 8 analyses that I did. I did the analyses 9 on -- on these observed results. 10 Q. Okay. Would you agree that 11 most of these risk ratios are between 12 approximately 1.1, some higher, some 13 lower, and 1.5? 14 A. No. There are some that's 15 3.9, I see. 16 Q. Well, so my next point -- 17 A. You know that's for 18 concerning. 2.49. 19 Q. Right. 20 A. I see a .7. I see a .3. 21 Q. I said most of them. Most 22 of -- most of them are in the range of 23 1.1 to 1.5. Not all of them. I 24 wasn't -- I was clear about that.</p>

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<p>1 A. Well, you're right. 2 MS. MILLER: Objection. 3 Wait, is that a question? 4 MR. TISI: Yes. 5 BY MR. TISI: 6 Q. I'm asking you -- 7 MS. MILLER: Or just a 8 statement? That's a statement. 9 BY MR. TISI: 10 Q. I'm asking you, were -- are 11 most -- most of these results are between 12 1.1 and 1.5, true? 13 A. So I would say that the 14 statement you made, however you define 15 most, I'm not quite sure, look like that 16 could be true, yes. 17 MS. MILLER: Is this a good 18 time for a break? 19 MR. TISI: Let me just -- 20 THE WITNESS: Yeah. 21 MS. MILLER: My head is 22 pounding. 23 THE WITNESS: So is mine, 24 actually.</p>	<p>1 THE VIDEOGRAPHER: All 2 right. The time is 3:35 p.m. off 3 the record. 4 (Short break.) 5 THE VIDEOGRAPHER: We are 6 back on the record. The time is 7 3:51 p.m. 8 BY MR. TISI: 9 Q. Doctor, we were talking 10 before the break about role of 11 statistical significance and the issue of 12 consistency. Do you remember that? 13 A. I know that we were talking 14 about consistency and statistical 15 significance, yes. 16 Q. Okay. I'm going to hand you 17 another chapter from Rothman's textbook. 18 I'll have that marked as the 19 next exhibit. 20 MR. SOILEAU: Which will be 21 27. 22 (Document marked for 23 identification as Exhibit 24 Ballman-27.)</p>
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<p>1 MS. MILLER: Soon as the 2 statistics started my head started 3 hurting. 4 MR. TISI: Let me just -- 5 let me just finish this, like, one 6 or two sentences, if you don't 7 mind. 8 MS. MILLER: Sure. 9 BY MR. TISI: 10 Q. Now, you said before on Page 11 17 -- on Page 17, "However, adequately 12 powered studies do not achieve 13 statistical significance, that is 14 evidence of inconsistency." 15 A. That is correct. 16 Q. So you are relying on the 17 statistically significant metric as part 18 of your analysis of consistency, true? 19 A. I am, or you could put it 20 another way and say that all of the 21 adequately powered studies would have to 22 have as their lower bound above 1.0. 23 MR. TISI: Okay. That's 24 fine. Let's take a break.</p>	<p>1 BY MR. TISI: 2 Q. Give that to your counsel. 3 Now, there is a section here on 4 consistency in the Bradford Hill 5 criteria, and it starts on Page 25 of 30. 6 Do you see that? 7 A. So causal criteria is on 8 this page, and strength. 9 Q. Correct. That's the section 10 that talks about Bradford Hill. Do you 11 see that? He refers to Bradford Hill, a 12 commonly used set of criteria was based 13 on a list of considerations or viewpoints 14 composed by Sir Bradford Hill. That's 15 the second paragraph there. 16 Do you see that? 17 A. Yes, I do. 18 Q. Okay. And he then goes 19 through the nine aspects. I'm just 20 orienting you here. There's a section on 21 consistency. 22 Do you see that? 23 A. Yes. 24 Q. Okay. Feel free to look at</p>

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<p style="text-align: right;">Page 442</p> <p>1 it if you want. It's only two 2 paragraphs. But I'm going to focus on 3 the second paragraph. First of all, 4 consistency is not a necessary criteria 5 according to Dr. Rothman, right? 6 MS. MILLER: Have you read 7 this? 8 THE WITNESS: No, I'm still 9 reading. Okay, I've read it. 10 BY MR. TISI: 11 Q. Okay. Does he not say, in 12 the second paragraph, "One mistake in 13 implementing the consistency criterion is 14 so common it deserves special attention. 15 It is sometimes claimed that a literature 16 or set of results is inconsistent simply 17 because some results are statistically 18 significant and some are not. 19 "This sort of evaluation is 20 completely fallacious, even if one 21 accepts the use of significance testing 22 methods." 23 Did I read that correctly, 24 first of all?</p>	<p style="text-align: right;">Page 444</p> <p>1 studies for power in the talc litigation? 2 A. I did not. 3 Q. You did not. So you don't 4 know whether they were adequately powered 5 or not, do you? 6 A. I -- I did not go through 7 and do a powered calculation for the 8 studies. 9 Q. So you can't determine 10 whether or not you applied that rule 11 correctly because you don't know whether 12 or not these were adequately powered 13 studies or not, do you? 14 A. I don't know if it was a 15 rule. I'm just saying that this is one 16 aspect of consistency. That's what I 17 said. 18 Q. Okay. So do you agree with 19 Dr. -- Dr. Rothman that just because some 20 studies are not statistically significant 21 and others are, it does not make them 22 inconsistent? 23 A. So what is adequately 24 powered is if one does a meta-analyses of</p>
<p style="text-align: right;">Page 443</p> <p>1 A. That is what it says. 2 Q. Okay. Do you agree with 3 that? 4 A. So it also says that -- 5 Q. I'm asking whether you agree 6 with that statement. Okay. Do you agree 7 with it? 8 A. Well, I do not agree with 9 it. And I'm going to explain why. 10 Q. Okay. 11 A. It goes on to -- well, it 12 says that -- I agree with it in some 13 sense. In the sense that the results -- 14 effect estimates from a set of studies 15 could all be identical even if they -- 16 many were -- many were significant and 17 many were not, the difference in 18 significance arising solely because of 19 differences in the standard error or 20 sizes of the study. 21 And if you recall, I said 22 adequately powered studies, which is what 23 he made this statement here. 24 Q. Did you analyze each of the</p>	<p style="text-align: right;">Page 445</p> <p>1 all the case-control studies and one does 2 a meta-analyses of all the cohort 3 studies. 4 Q. I didn't ask you that 5 question, respectfully. Okay. My 6 question was -- 7 MS. MILLER: Try not to 8 interrupt her. 9 BY MR. TISI: 10 Q. Do you agree -- 11 MS. MILLER: It's so tiring. 12 MR. TISI: No, it is -- 13 listening to her speechify is 14 really disrupting. 15 MS. MILLER: That's the pot 16 calling the kettle black. 17 BY MR. TISI: 18 Q. Do you agree with 19 Dr. Rothman that because some studies are 20 not statistically significant and others 21 are, it does not make them inconsistent? 22 Do you agree with that statement as a 23 general proposition? 24 MR. LOCKE: Objection.</p>

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<p style="text-align: right;">Page 446</p> <p>1 THE WITNESS: It depends. 2 BY MR. TISI: 3 Q. Okay. And it depends upon 4 the power, correct? 5 A. No. It depends upon the 6 situation, as I was trying to explain and 7 you wouldn't let me finish. 8 Q. Okay. Does it depend upon 9 the power of the study to detect an 10 association? 11 A. You mean a statistically 12 significant association? 13 Q. Yes. 14 A. That is what power is about. 15 Q. Correct. Okay. The study, 16 each study has to be powered to find the 17 association, correct, adequately powered? 18 A. No. Just because a study is 19 adequately powered, it could not find an 20 association because there really is no 21 real relationship there. 22 Q. Let's go to Exhibit Number 23 23. Again, this was Dr. Rothman's six 24 misconceptions.</p>	<p style="text-align: right;">Page 448</p> <p>1 A. No. That's not what I'd 2 done. I would like some time please to 3 read the rest of this. 4 Q. Sure. 5 A. He does say, "Focusing on 6 the magnitude" -- 7 Q. Just -- I thought you were 8 going to read the whole -- I thought you 9 were going to read the whole thing. 10 Let's read the whole thing and we can 11 talk about it. Thank you. 12 A. Okay. 13 MS. MILLER: It would be 14 really nice if you would not talk 15 over the witness. 16 MR. TISI: It would be 17 really nice if she'd -- 18 MS. MILLER: It's especially 19 offensive for the way you are 20 talking to her. 21 MR. TISI: Okay. You know, 22 I find it offensive that a witness 23 would come in here, and I ask her 24 whether or not this pen is red and</p>
<p style="text-align: right;">Page 447</p> <p>1 A. Yes. 20. 2 Q. Exhibit 20. I'm sorry. Go 3 to Misconception Number 6. Can you read 4 what it is? 5 A. Okay. 6 Q. Could you read -- could you 7 read it for the record, Misconception 8 Number 6? 9 A. Oh, read it out loud? 10 Q. Yes. 11 A. Just that piece? 12 Q. Just what the misconception 13 is, and we can talk about what he says. 14 A. Okay. It says, 15 "Misconception 6. Significance testing 16 is useful and important for the 17 interpretation of data." 18 Q. Okay. Is that what -- isn't 19 that what you've done here, is you've 20 looked at, you've looked at which studies 21 are statistically significant and which 22 ones aren't, and you've said that they 23 were inconsistent and, therefore, you did 24 not find inconsistency?</p>	<p style="text-align: right;">Page 449</p> <p>1 she talks about all the reasons 2 why the blue pen down the table is 3 blue. Okay. I find that 4 offensive. That's not the way 5 this works. 6 MR. LOCKE: Objection. 7 MS. SHARKO: That's not what 8 happened. That's not what just 9 happened. 10 MS. MILLER: You just kicked 11 me again. I hope you're not doing 12 that on purpose. 13 MR. TISI: I'm definitely 14 not doing it on purpose. I would 15 not do that. And you kicked me 16 before, and I said nothing about 17 it. 18 MS. MILLER: I don't think 19 my legs are long enough. 20 MR. TISI: Well, if they 21 aren't long enough, how did I -- 22 THE WITNESS: Okay. Is 23 there a question? 24 BY MR. TISI:</p>

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<p style="text-align: right;">Page 450</p> <p>1 Q. Yes. So my question is, 2 Doctor, didn't you -- wasn't the issue of 3 which studies were statistically 4 significant and which ones weren't, 5 wasn't that an important factor in your 6 discussion of the talc studies in the 7 context of the consistency aspect of 8 Bradford Hill? 9 MR. LOCKE: Objection. 10 THE WITNESS: So when I 11 looked at the analyses for 12 consistency, just for sake of 13 argument, to go through this 14 quickly, let's -- I look at the -- 15 the meta-analyses of the 16 case-control studies, which is 17 statistically significant. 18 I looked at the 19 meta-analyses of the cohort 20 studies, which show no significant 21 association. And that is an 22 inconsistency. 23 BY MR. TISI: 24 Q. Okay. So the determining</p>	<p style="text-align: right;">Page 452</p> <p>1 Q. All right. Both of those if 2 you're just looking at the risk ratios 3 are positive, correct? 4 MR. LOCKE: Objection. 5 BY MR. TISI: 6 Q. 1.02 to 1.06 is a positive 7 risk ratio, correct? 8 MS. MILLER: Objection. 9 THE WITNESS: But -- but -- 10 they are positive. But again, I 11 don't see where this is playing 12 into -- 13 BY MR. TISI: 14 Q. I'm asking you the question. 15 Okay. The difference is one is 16 statistically significant result and the 17 other one is not. And you make a point 18 of that in this sentence, correct? 19 A. And that follows the point I 20 made above, which also plays into my 21 consistency is that Berge found there was 22 a statistically significant different 23 association for the perineal talc 24 powder -- or perineal/genital talc powder</p>
<p style="text-align: right;">Page 451</p> <p>1 factor, because even the cohort studies 2 had a positive risk ratio, correct? 3 A. I don't know why that plays 4 into anything. 5 Q. Well, okay. They both 6 showed a positive -- they were in your 7 report on Page 26. It was 1.02 to 1.06, 8 whereas the statistically significant 9 results from the case-control studies 10 were 1.26 to 1.35. 11 MS. MILLER: When you say 12 "they both," what are you 13 referring to? 14 BY MR. TISI: 15 Q. Okay. On Page 26 of your 16 report, you say, "There is clear 17 inconsistency between different study 18 designs with the case-control studies 19 yielding a statistically significant 20 association ranging from 1.26 to 1.35, 21 and cohort studies yielding a 22 nonstatistically significant association 23 ranging from 1.02 to 1.06, correct? 24 A. That is what it says there.</p>	<p style="text-align: right;">Page 453</p> <p>1 exposure and ovarian cancer between the 2 case-control studies and the cohort 3 studies. 4 Q. And he's looking at 5 P-values, right. P-.07? 6 A. Yeah. He is looking at 7 P-values, and that is what most of 8 medical literature does and bases their 9 evidence on. 10 And I looked -- and then I 11 look at the magnitude of the differences 12 between the two, and I do see that they 13 are different. 14 Q. Did you look to see whether 15 the confidence intervals overlapped? 16 A. What confidence intervals? 17 Q. Well, if you go above. The 18 same results here, if you go above in 19 your paragraph, it says 1.26, 95 percent 20 confidence interval 1.17 to 1.35. 21 Do you see that? You're 22 basically talking about the same dataset. 23 A. What do you mean the same 24 dataset?</p>

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<p style="text-align: right;">Page 454</p> <p>1 Q. If you go above, you said 2 1.26 to 1.35. But above, you're 3 including the confidence intervals, 4 correct? 5 A. Yes. 6 Q. Okay. The confidence 7 intervals for all of those results cross 8 1.2, for each and every one of them, 9 don't they? 10 A. I don't know how that's 11 relevant. 12 Q. I know you don't. I'm 13 asking you do they all cross 1.2? Do all 14 the confidence intervals for every one of 15 these risk ratios have 1.2 in the 16 confidence interval? 17 A. Well, I don't know what you 18 mean by in. The one from 1.02 goes from 19 .85 to 1.2. I suppose you could call 20 that in it. 21 But, yeah, if you look at 22 ranges, other than the one that it's on 23 the actual point, the ranges would 24 contain 1.2.</p>	<p style="text-align: right;">Page 456</p> <p>1 page of -- 2 Q. At the -- page -- on the 3 last page. 4 A. In the conclusions? 5 Q. Yeah, 102 -- 10 -- 6 A. Okay. I'm sorry. I didn't 7 understand. 8 Q. No, that's fine. I should 9 have oriented you. I apologize. 10 A. So the last sentence in the 11 conclusion? 12 Q. Right. And I'll read it. 13 A. Okay. 14 Q. "Why do such important 15 misconceptions about research" -- 16 A. Wait, wait, the last 17 sentence in the conclusion? Mine says 18 to the extent -- 19 Q. I'm on the conclusions. I'm 20 on the conclusions. The very -- 21 A. Oh, the first sentence. 22 Yes. 23 Q. "Why do such important 24 misconceptions about research persist?"</p>
<p style="text-align: right;">Page 455</p> <p>1 Q. Okay. So all of these 2 reports are consistent in that the 3 confidence intervals include 1.2, would 4 you agree with that? 5 MR. LOCKE: Objection. 6 THE WITNESS: No I would not 7 agree with that whatsoever. 8 BY MR. TISI: 9 Q. Okay. So let me go back to 10 Dr. Rothman's statement in -- in the 11 conclusion that he says -- in the 12 conclusionary statement of his six 13 misconceptions, persistent research 14 misconceptions. 15 He says, "It's easy to 16 declare a result is not statistically 17 significant, falsely implying that there 18 is no indication of an association" -- 19 A. I -- I'm sorry. I'm just 20 stopping you because I really don't know 21 where you're reading from. 22 Q. It's the last of the 23 conclusion sentence. 24 A. Conclusion section on what</p>	<p style="text-align: right;">Page 457</p> <p>1 To a large extent these misconceptions 2 represent substitutes for more thoughtful 3 and difficult tasks. It's simpler to 4 resolve a discrepancy between a trial and 5 a non-experimental study in favor of a 6 trial without undertaking a laborious 7 analysis that Herman, et al., did. It's 8 easier to declare that a result is not 9 statistically significant, falsely 10 implying that there is no indication of 11 an association, rather than consider 12 quantitatively the range of associations 13 that the data actually support." 14 Do you see that? 15 A. I -- that those are what -- 16 those are the words. 17 Q. Okay. And the range of 18 associations for the data is represented 19 by the confidence intervals, correct? 20 A. Now, where are you reading 21 that? 22 Q. I'm asking you that 23 question. The range of associations in 24 any reported study is the numbers that</p>

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<p style="text-align: right;">Page 458</p> <p>1 are between the confidence intervals? 2 MS. MILLER: Objection. 3 THE WITNESS: That's not 4 necessarily true. In the 5 meta-analyses, we have the range 6 of associations of the point 7 estimates. Those are not 8 confidence intervals. 9 MADAM COURT REPORTER: 10 Chris, can we go off the record 11 for a second, just briefly? 12 THE VIDEOGRAPHER: The time 13 is 4:07 p.m. Off the record. 14 (Brief pause.) 15 THE VIDEOGRAPHER: We are 16 back on the record. The time is 17 4:12 p.m. 18 BY MR. TISI: 19 Q. Doctor, isn't it true, that 20 the statistical -- the statistics 21 community has abandoned the looking only 22 at -- looking at statistical significance 23 in favor of looking at where the 24 confidence intervals are on studies in</p>	<p style="text-align: right;">Page 460</p> <p>1 week. I have not read that. 2 So did you give me that 3 statement so I can -- 4 Q. I haven't yet. I'm going to 5 do it. But it's not just this week. Did 6 you know in 2016 the American Statistical 7 Association was so concerned about the 8 misuse of statistical significance in 9 P-values that it took the extraordinary 10 step, never before taken before, and 11 never before taken since, to issue a 12 statement about the misuse of P-values 13 and statistical significance? 14 A. If you say that's true, I 15 would have to see what that statement was 16 at that time. 17 Q. Had you ever -- had you ever 18 heard of that? 19 A. I -- 20 MS. MILLER: Objection. 21 THE WITNESS: I heard 22 that -- I may have heard there was 23 a P-value statement. But again, I 24 didn't read it.</p>
<p style="text-align: right;">Page 459</p> <p>1 terms of making decisions about things 2 like causation? 3 MR. LOCKE: Objection. 4 THE WITNESS: So there's two 5 different questions there. The 6 first I heard, isn't it true that 7 the statistical community 8 abandoned using P-values for 9 statistical significance. 10 And I -- I don't think I -- 11 I'm not sure what you mean by the 12 statistical community. But I know 13 in the medical literature and all 14 studies that I've worked on and 15 all studies that I published, we 16 had P-values in them. 17 So I don't know who you mean 18 by the statistical community 19 abandoning P-values. 20 BY MR. TISI: 21 Q. Well, what about the 22 American Statistical Association? 23 A. Well, you told me that there 24 was a statement that was just out this</p>	<p style="text-align: right;">Page 461</p> <p>1 BY MR. TISI: 2 Q. You didn't know that? 3 Somebody as accomplished as you in the 4 scientific and statistical community, you 5 don't know when the American Statistical 6 Association position, as a member, what 7 the position is on P-values and 8 statistical significance? 9 MR. LOCKE: Objection. 10 THE WITNESS: I said I 11 haven't read the statement. 12 BY MR. TISI: 13 Q. Did you not know that it 14 even existed before I brought it up to 15 you? 16 A. Again, I didn't know what 17 type of statement it is and the way you 18 characterized it. As I said, I think I 19 heard there was some things on 20 P-values -- 21 Q. Did you bother to look it 22 up? 23 A. I'm on Listservs. 24 No, I did not look it up.</p>

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<p>1 MS. MILLER: Objection.</p> <p>2 BY MR. TISI:</p> <p>3 Q. So having heard there was a</p> <p>4 statement about statistical significance</p> <p>5 and P-values by the American Statistical</p> <p>6 Association, it wasn't important for you</p> <p>7 to look it up and see, well, what do my</p> <p>8 colleagues say about this?</p> <p>9 A. I don't think it's a matter</p> <p>10 of importance. I think it's a matter of</p> <p>11 time. And you know, I -- when that came</p> <p>12 out, I may have thought, oh, that's</p> <p>13 something worth looking at. But, you</p> <p>14 know, my time got consumed by more</p> <p>15 pressing matters, and I never got to it.</p> <p>16 Q. This came out in 2016. This</p> <p>17 is 2019. You mean you had no time in the</p> <p>18 past three years to look at a</p> <p>19 two-three-page statement about the misuse</p> <p>20 of P-values and statistical significance?</p> <p>21 MS. MILLER: Objection.</p> <p>22 THE WITNESS: That's not</p> <p>23 what I said or meant. What I</p> <p>24 meant is that at the time it came</p>	<p>1 because all the studies I looked</p> <p>2 at were talking about statistical</p> <p>3 significance. So it would be odd</p> <p>4 if I didn't talk about statistical</p> <p>5 significance.</p> <p>6 Can you show me a report</p> <p>7 where there wasn't a P-value in</p> <p>8 the studies I reviewed.</p> <p>9 BY MR. TISI:</p> <p>10 Q. I'm asking you the</p> <p>11 questions. I'm asking you the questions.</p> <p>12 And the question that I'm asking you is,</p> <p>13 since you were doing a whole causation</p> <p>14 analysis, looking at the totality of the</p> <p>15 evidence, 30-some odd studies and dealing</p> <p>16 with an issue of consistency, and relying</p> <p>17 on statistical significance, not for one</p> <p>18 study, but looking across studies,</p> <p>19 looking across design, did you not think</p> <p>20 it important to say, you know, I remember</p> <p>21 that the American Association for --</p> <p>22 American Statistical Association came out</p> <p>23 with this really unique statement. Maybe</p> <p>24 I ought to pick it up and take a look at</p>
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<p>1 out, I likely thought, oh, if I</p> <p>2 ever have a spare minute, this</p> <p>3 would be something interesting to</p> <p>4 look at. But I don't think I came</p> <p>5 out with -- I -- the spare minute</p> <p>6 probably may have happened later.</p> <p>7 But by that point, I had forgotten</p> <p>8 about it.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Well, in the interim you had</p> <p>11 written two reports, one in</p> <p>12 Viagra/Cialis -- Cialis outside of your</p> <p>13 work and one here for 56 hours or</p> <p>14 whatever it happened to be.</p> <p>15 And you mentioned</p> <p>16 statistical significance a lot in your</p> <p>17 report.</p> <p>18 Could you have taken one of</p> <p>19 those hours to look up what the American</p> <p>20 Statistical Association says about</p> <p>21 statistical significance?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I'm not sure</p> <p>24 how that would be relevant,</p>	<p>1 it?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 THE WITNESS: Again, I don't</p> <p>4 see how that's relevant, because</p> <p>5 to do the analyses I've done, I</p> <p>6 rely upon how the papers report</p> <p>7 their results and so forth. And I</p> <p>8 can't impose sort of a different</p> <p>9 way for them to analyze their</p> <p>10 data.</p> <p>11 BY MR. TISI:</p> <p>12 Q. They didn't do -- they</p> <p>13 didn't do Bradford Hill tests, did they?</p> <p>14 You did. You did in this litigation.</p> <p>15 All the studies, very -- none of these</p> <p>16 studies did a Bradford Hill -- Bradford</p> <p>17 Hill analysis, but you did, true?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: I don't know</p> <p>20 how P-values are relevant just to</p> <p>21 Bradford Hill. I don't get that.</p> <p>22 BY MR. TISI:</p> <p>23 Q. You applied your own</p> <p>24 independent -- independent expertise as a</p>

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<p>1 statistician at a medical university and 2 you are unaware what the American 3 Statistical Association says about 4 P-values? 5 MS. MILLER: Objection. 6 THE WITNESS: Again, I 7 looked at all the literature that 8 exists. And I -- I used the 9 Bradford Hill criteria to 10 determine whether or not there is 11 a causal relationship between 12 perineal talc exposure and ovarian 13 cancer. 14 And the methodology that I 15 used is the methodology that all 16 others use. And so I don't see 17 the relevance of having to look 18 up -- or I don't see the relevance 19 of looking up a statement on 20 P-values to do that analyses. 21 BY MR. TISI: 22 Q. You know that looking at the 23 plaintiffs' experts reports they -- you 24 clearly were critical of the plaintiffs'</p>	<p>1 Q. Is that a criticism -- 2 MS. MILLER: And also talk 3 over me. 4 MR. TISI: I'm going to talk 5 because -- 6 MS. MILLER: Do you just 7 talk over all women? 8 MR. TISI: Oh, please don't 9 do that to me. I have no problem 10 with you -- with you objecting. 11 But your constant speaking 12 objections are -- are really 13 overboard. 14 BY MR. TISI: 15 Q. Doctor -- 16 MS. SHARKO: I don't think 17 the record will demonstrate that. 18 MR. TISI: I think the 19 record will demonstrate that. 20 BY MR. TISI: 21 Q. Doctor, did you -- isn't one 22 of your criticisms of the plaintiffs' 23 experts, one of them, is that they -- 24 they were looking at the point estimate</p>
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<p>1 experts for looking at the point 2 estimates and not considering the -- 3 whether a study was statistically 4 significant or not, true? 5 A. Can you point me to -- 6 Q. I'm asking whether that's 7 true. We can go through it. I'm asking 8 you, was that -- or is that one of your 9 criticisms? 10 A. Well, you told me that was a 11 criticism. 12 Q. Is it a criticism? 13 A. I'm asking you show me in my 14 report where that -- 15 Q. Is that a criticism? 16 A. I can't -- 17 MS. MILLER: Please don't 18 talk over the witness. 19 BY MR. TISI: 20 Q. Is that -- is that a 21 criticism of yours -- 22 MS. MILLER: How many times 23 do I have to say it? 24 BY MR. TISI:</p>	<p>1 and not the -- of these studies for 2 consistency, and not considering whether 3 or not they were statistically 4 significant or not? I'm asking you, is 5 that -- as you sit here today, is that 6 one of your criticisms? 7 A. I'm asking you to point that 8 out to me, because you -- 9 Q. I'm asking you -- I'm asking 10 you, is that one of your criticisms? 11 A. I -- I'll have to read 12 through all my criticisms. I'm happy to 13 do so. 14 Q. I thought you would have 15 done that in preparation for today. 16 A. Yeah, and I'm tired. And 17 it's a long day, and I don't -- I did not 18 memorize my, you know, 40-some-page 19 report. So I will -- 20 Q. When's the last time you -- 21 A. I will take the time and go 22 through and -- 23 Q. When was the last time that 24 you read it before today?</p>

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<p style="text-align: right;">Page 470</p> <p>1 MS. MILLER: She's in the 2 middle of a sentence again. 3 BY MR. TISI: 4 Q. When's the last time you 5 read it before today? 6 MR. TISI: This is a 7 filibuster, and you know it. 8 THE WITNESS: I'm trying to 9 answer your question. And you're 10 asking me if I made that 11 criticism. And I'm saying that I 12 can't remember off the top of my 13 head. 14 BY MR. TISI: 15 Q. Okay. 16 A. And if you know where it is 17 in here, that I made that criticism, I 18 ask for the help. You said no, I'm not 19 going to do that. You need to remember 20 that. And -- 21 Q. I didn't say that. 22 A. Well, that's how I 23 interpreted it. 24 Q. Okay.</p>	<p style="text-align: right;">Page 472</p> <p>1 MS. MILLER: Would you like 2 me to re-read? 3 MR. TISI: No. She's not 4 asking to re-read. You are. 5 THE WITNESS: Well, I am. I 6 am. I'm confused. What is the 7 question? 8 BY MR. TISI: 9 Q. Doctor -- doctor -- okay. 10 Do you have an opinion to a reasonable 11 degree of scientific certainty that the 12 plaintiffs' experts were wrong and used 13 an improper methodology if they looked at 14 the point estimates for consistency and 15 did not consider statistical 16 significance? If that was shown to be 17 true, would that be wrong? 18 A. I think if someone only 19 looked at point estimates and did not 20 look at statistical significance, that 21 would be incorrect. 22 Q. Okay. What if they looked 23 at the point estimate and the confidence 24 interval, irrespective of statistical</p>
<p style="text-align: right;">Page 471</p> <p>1 A. And then I said, well, okay, 2 then I'll have to go through and read to 3 see if I made that criticism. 4 Q. Okay. As you sit here 5 today, okay, because honestly, I don't 6 have the time to go through this. But I 7 know it's in there. 8 A. Well, then please show it to 9 me. 10 Q. I said I know it's in there, 11 and I don't have the time to go through 12 it. But I'm asking you, as you sit here 13 today, do you have an opinion to a 14 reasonable degree of scientific certainty 15 that the plaintiffs' experts were wrong 16 and used an improper methodology if they 17 looked at the point estimates and did not 18 consider statistical significance? If 19 that were shown to be true, would that be 20 wrong? 21 MS. MILLER: Objection. If 22 what was shown to be true? 23 MR. TISI: Read the 24 question, Counsel.</p>	<p style="text-align: right;">Page 473</p> <p>1 significance? 2 A. Again, I'd have to see the 3 analyses. The analyses that I looked at 4 in terms of consistency was 5 methodologically flawed. 6 Q. Okay. Let's look at the ASA 7 statement on P-values. If you go to the 8 "ASA statement on P-values: Context and 9 purpose, the editorial." 10 Do you see that? Second 11 page. 12 A. I don't have that document. 13 Q. It's right in front of you, 14 I believe. 15 A. 28? 16 Q. Mm-hmm. 17 A. Second page? 18 Q. Yep. It says, "ASA 19 statement on P-values: Context, process, 20 and purpose." 21 A. Okay. 22 Q. And if you go down -- and 23 I'm just going to ask you one question 24 here, so I don't think it's necessary for</p>

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<p style="text-align: right;">Page 474</p> <p>1 you to read the whole thing. 2 It says, "When the ASA board 3 decided to take up" -- at the very last 4 paragraph at the bottom of the left 5 column. "When the ASA board decided to 6 take up the challenge of developing 7 policy statements on P-values and 8 statistical significance, it did so 9 recognizing this was not a lightly taken 10 step. The ASA has not previously taken 11 positions on specific matters of 12 statistical practice." 13 Is that true? I mean, is 14 that -- did I read that correctly? 15 A. You read the words, yes. 16 Q. Okay. Have you ever seen 17 the ASA do -- issue a statement other 18 than what I've just presented you here, 19 about statistical practice? 20 A. Well, they state that they 21 previously -- have not previously taken 22 positions. So if what they are saying is 23 true, there would be nothing to see. 24 Q. Okay. And if you look at</p>	<p style="text-align: right;">Page 476</p> <p>1 please? 2 Q. Page 131. We are at the 3 bottom, 63.4. 4 A. Okay. Yes, I'm there. 5 Q. Do you see Number 2 where it 6 says, "P-values" -- and let me ask you if 7 this is a true statement or not. 8 "P-values do not measure the probability 9 that a study hypothesis is true or the 10 probability that the data was produced by 11 random chance alone." 12 Do you see that? 13 A. Yes, I do. 14 Q. Okay. It says, "Researchers 15 often wish to turn P-values into a 16 statement the truth of a null hypothesis 17 or about the probability that random 18 chance produced the overall data. The 19 P-value is neither. It is a statement 20 about the data in relation to a specified 21 hypothetical explanation and it is not a 22 statement about the explanation itself." 23 Is that true? 24 A. Yeah, I -- I'll have to</p>
<p style="text-align: right;">Page 475</p> <p>1 the next page, some of the people who 2 were involved in this are, among other 3 people, Sander Greenland, and Kenneth 4 Rothman. You see their names there? 5 A. I'm sorry. Where are you? 6 Q. Next page. Do you see the 7 bullet points on the right? 8 A. Yeah. There's a list of 9 individuals. Yes, I see that. 10 Q. Among them Sander Greenland, 11 Kenneth Rothman, the two people that 12 we've been talking about all day, 13 correct? 14 A. So, again, can you point 15 me -- you mean these bullets? 16 Q. Yeah. 17 A. Well, these are references. 18 Q. Okay. All right. If you go 19 to the next page, the ASA statements on 20 statistical significance. 21 A. On what page? Could you 22 just -- 23 Q. Next page. 24 A. -- say the page number,</p>	<p style="text-align: right;">Page 477</p> <p>1 parse it in different ways. 2 So it is true that the 3 P-value is not the truth about a 4 hypothesis. To calculate a P-value, you 5 need to assume the hypothesis is true. 6 Therefore, it can't be the 7 probability that the hypothesis is true 8 because you assumed it was true. So, 9 yes, I agree with that. 10 Q. But it also says -- 11 THE VIDEOGRAPHER: Chris, 12 watch your -- watch your 13 microphone. Sorry. 14 BY MR. TISI: 15 Q. But it also says it is not a 16 statement of the truth of the null 17 hypothesis. 18 A. That's what I mean. You're 19 assume the null hypothesis is true in 20 order to calculate a P-value. So 21 therefore the P-value cannot be the 22 probability the null hypothesis is true 23 because that was the assumption to get 24 the P-value.</p>

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<p style="text-align: right;">Page 478</p> <p>1 Q. The next statement is 2 "Scientific conclusions and business 3 policy decisions should not be based only 4 on whether a P-value passes a specific 5 threshold. Practices that reduce data 6 analysis to scientific inferences to 7 mechanical bright-line rules, i.e., 8 P-value .05 for justifying scientific 9 claims and conclusions, can lead to 10 enormous beliefs and poor decisionmaking. 11 "A conclusion does not 12 immediately become true on one side of 13 the divide and false on the other." 14 Do you agree with that? 15 A. I agree that you read the 16 sentence. And I go on, and what makes 17 me -- this true is researchers should 18 bring many contextual factors into play 19 to derive scientific inferences, 20 including the design of a study, the 21 quality of the measurements, the external 22 elements for the phenomenon under study, 23 and the validity of the assumptions that 24 underlie the data analysis. And to me,</p>	<p style="text-align: right;">Page 480</p> <p>1 sentence says -- 2 A. No, no, no. Very end of 3 what? 4 Q. The very end of the 5 conclusion section. 6 A. On a different page now? 7 Q. On a different -- next page. 8 The next sentence says, "No single index 9 should substitute for scientific 10 reasoning." 11 Do you agree with that? 12 A. I haven't -- again, that's 13 taken out of context. I agree with the 14 whole thing that's, "Good statistical 15 practice is an essential component of 16 good scientific practice, emphasizes 17 principles of good study design and 18 conduct, a variety of numerical and 19 graphical summaries of data, 20 understanding the phenomenon under study, 21 and interpretation of results in context, 22 complete reporting and proper and logical 23 quantitative understanding of what the 24 data summaries mean."</p>
<p style="text-align: right;">Page 479</p> <p>1 this sort of encompasses what the 2 Bradford Hill framework is doing. 3 Q. And let's read the rest of 4 it. It goes on to say, "Pragmatic 5 considerations often require binary yes 6 and no decisions, but does not mean that 7 the P-value alone can ensure that a 8 decision is correct or incorrect. The 9 widespread use of statistical 10 significance, generally interpreted as a 11 P-value less than or equal to .05, is a 12 license for making a claim of a 13 scientific finding or implied truth, 14 leads to considerable distortion of the 15 scientific process." 16 Is that true or not? 17 A. That is true in the context 18 of what they mean in that you cannot use 19 a single study to say this study was 20 statistically significant, therefore, I 21 have proven something scientifically, a 22 single study. 23 Q. Okay. At the very end of 24 it, on conclusion, it says -- at the last</p>	<p style="text-align: right;">Page 481</p> <p>1 Q. And then the next sentence 2 says? 3 A. "No single index" -- I don't 4 know what they're referring to there. It 5 doesn't say the P-value alone -- "should 6 substitute for scientific reasoning." It 7 says no single index. It could be any 8 index, the mean. 9 Q. Now, do you know that the 10 American Statistical -- and you were not 11 asked to be on this panel, I assume, 12 since you didn't even know that -- you 13 hadn't even read it. So you were not on 14 this panel. You were not asked by your 15 colleagues to participate in this, 16 correct? 17 MS. MILLER: Objection. 18 Please let me object. 19 THE WITNESS: Could you show 20 me who was on the panel? 21 BY MR. TISI: 22 Q. I'm just asking you, were 23 you asked to be on this panel? 24 A. I -- I -- yeah, I don't know</p>

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<p>1 how -- who is on the panel and how many 2 people are on the panel. 3 Q. I didn't ask you that. 4 A. But I have a feeling that 5 there are many people that weren't on the 6 panel. 7 Q. I didn't ask that. I asked 8 whether you were asked to be on the 9 panel. 10 A. No, I was not asked to be on 11 the panel. 12 Q. That was the answer to the 13 question. Thank you. 14 Next question is -- now, I 15 represented to you that this week the 16 American -- you know, -- do you get the 17 journal, the American Statistician? 18 A. Yes. 19 Q. It's probably the most 20 important journal in the statistical -- 21 in the field of statistics. Would you 22 agree? 23 MS. MILLER: Objection. 24 BY MR. TISI:</p>	<p>1 important statistics journal that there 2 is. I think it depends upon -- no. I -- 3 Q. Did you know just this week, 4 as I indicated, that the journal devoted 5 its entire volume to the issue of 6 statistical significance? 7 A. So this week's journal? 8 Q. Mm-hmm. 9 A. And, you know, I don't even 10 know if I had been in my office to get 11 it. So I am not aware of that. 12 Q. You weren't aware that it 13 was coming out, were you? 14 A. I don't know why I would be 15 aware that it's coming out. 16 Q. Sometimes if something big 17 is happening in the world of statistics, 18 kind of a lot of people involved, it gets 19 out that they are putting together a 20 volume devoted to a specific topic. 21 You didn't -- you were 22 unaware of it? 23 A. I -- well, I -- I don't know 24 if that statement is true or not. I</p>
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<p>1 Q. It's a high-impact journal 2 within that field? 3 MS. MILLER: Objection. 4 THE WITNESS: Wait, what's 5 the journal again? 6 (Document marked for 7 identification as Exhibit 8 Ballman-28.) 9 BY MR. TISI: 10 Q. The American -- the 11 American -- what's the journal of the 12 American Statistical Society? 13 A. What is the journal? The 14 journal -- JASA. 15 Q. Yeah. Actually, just give 16 me the -- I'm sorry. I apologize. 17 A. JASA, I believe, is the 18 Journal of ASA. The Journal of the 19 American Statistical -- 20 Q. It's the American 21 Statistician. The American Statistician. 22 A. Yeah, that's sort of a -- I 23 get that journal. I don't know if people 24 would characterize it as the most</p>	<p>1 mean, I know in JCO, we put out very -- 2 we put out special issues. And I don't 3 think all of oncology is aware it's 4 coming out. 5 Q. So I'm going to show you in 6 the -- is the journal Science a good 7 journal? Sorry. Nature. I'm sorry. 8 A. Yes. Nature is a very good 9 journal. 10 Q. The entire ASA journal was 11 devoted to 43 studies, 43 papers on this 12 topic. 13 MS. MILLER: What's ASA? 14 MR. TISI: The American 15 Statistical Association. 16 MS. MILLER: That's not a 17 journal. That's an association. 18 You said -- 19 MR. TISI: You're 20 interrupting me now. 21 MS. MILLER: Fine. 22 MR. TISI: Their journal is 23 the American Statistician. 24 MS. MILLER: I think she</p>

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<p>1 said that's not their journal. 2 THE WITNESS: No, I didn't 3 say that. 4 MS. MILLER: Oh, I 5 misunderstood. 6 THE WITNESS: I said I don't 7 believe it's the most important. 8 Could -- I don't know if 9 there's 40-some articles. 10 BY MR. TISI: 11 Q. I'm going to represent to 12 you that it is. 13 And I'm -- you know, you can 14 either believe me or not. My guess is at 15 some point this week, you may go home and 16 take a look at it. But I didn't bring 17 all 43 articles. And you'd want to read 18 them all anyway. So we don't have the 19 time to do that. 20 A. But I'd at least like to 21 look at the titles. 22 MR. TISI: Okay. Well, John 23 can you pull up the titles of the 24 43? If you can get them on your</p>	<p>1 MS. MILLER: Objection. 2 That was not read correctly. 3 BY MR. TISI: 4 Q. These three authors and more 5 than 800 signatories call for an end to 6 hyped claims and the dismissal of 7 possibly crucial effects. 8 Do you see that? 9 A. I see how that's stated 10 there. 11 Q. Okay. And I'm happy to give 12 you an opportunity to read it. And since 13 you haven't read it, and this will take a 14 moment, I'm happy to do it, but I am 15 going to focus your attention to certain 16 things. 17 Do you want to glance 18 through it, I'm more than happy to have 19 you glance through it, but we can do it 20 off the record. 21 MR. TISI: Go off the 22 record, please. 23 MR. LOCKE: No, no. 24 MR. TISI: That's what we've</p>
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<p>1 computer, please. 2 BY MR. TISI: 3 Q. But in the meantime, a 4 commentary related to this, this 5 publication was published in Nature by 6 Drs. Greenland, Blake McShane and 7 Valentin Amrhein. 8 (Document marked for 9 identification as Exhibit 10 Ballman-29.) 11 BY MR. TISI: 12 Q. Okay. Let me show you that. 13 Now, the title of this is "Retire 14 Statistical Significance." 15 Do you see that, Doctor? 16 A. It says "Retire Statistical 17 Significance." 18 Q. Okay. And actually, 19 underneath it says, Valentin Amrhein, 20 Sander Greenland, and Blake McShane, and 21 more 800 signatories, call for an end to 22 hyped up claims and dismissal -- 23 dismissal of possibly crucial effects. 24 Do you see that?</p>	<p>1 done -- if it's a long -- 2 MR. LOCKE: No, we have not. 3 MR. TISI: Yes, we have. 4 MR. LOCKE: No, we have 5 not-- 6 MR. TISI: Yes, we have. 7 Yes, we have. 8 MS. MILLER: I thought we go 9 off the record if it's something 10 the witness -- 11 MR. TISI: Hadn't seen, 12 yeah. 13 MS. MILLER: No, if it was 14 something the witness had cited 15 and a reference. But if it's 16 something the witness had never 17 seen before, I don't think we'd go 18 off -- 19 MR. TISI: No, that's what 20 we -- that's what we've been 21 doing. 22 MR. LOCKE: That's not what 23 we've been doing. 24 MR. TISI: That's exactly</p>

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<p style="text-align: right;">Page 490</p> <p>1 what we've been doing. 2 Anyway, she's looking at it. 3 BY MR. TISI: 4 Q. Let's go through. I'm going 5 to ask you to read down to the bottom of 6 the left-hand column. I'll ask you some 7 questions about that. 8 A. How far do you want me to 9 read? 10 Q. Just to the bottom of the 11 left-hand column? 12 A. Second page? 13 Q. Second page, correct. 14 A. Okay. Just the bottom of 15 that first column. 16 Q. Correct. 17 A. I have read that. 18 Q. Actually, and you can 19 continue to the next -- the first 20 paragraph on the next page. 21 MS. MILLER: The first 22 paragraph on the next column or 23 the -- 24 MR. TISI: Next column.</p>	<p style="text-align: right;">Page 492</p> <p>1 that I actually know is Sander 2 Greenland. I do not know who 3 Blake McShane is, nor Valentin 4 Amrhein. 5 BY MR. TISI: 6 Q. Do you know -- do you have 7 respect for Sander Greenland? 8 MS. MILLER: Objection. 9 THE WITNESS: Again, I know 10 his name. I know he's done -- you 11 know, he's authored some books and 12 so forth. 13 BY MR. TISI: 14 Q. So what they say here -- and 15 of course, I'm reading in the second 16 page. It says, "We agree" -- "We are far 17 from alone. We invited others to read 18 this draft" -- "read a draft of this 19 comment and sign their names if they 20 concurred with our message. 250 did so 21 within 24 hours. A week later, we had 22 more than 800 signatories, all checked 23 for academic affiliation or other 24 indication of present or past work in a</p>
<p style="text-align: right;">Page 491</p> <p>1 BY MR. TISI: 2 Q. Actually, you can read the 3 whole -- read the whole column up until 4 the next category. 5 A. Yes. I read it. 6 Q. So, Doctor, under the 7 section that says -- first of all, these 8 are all -- these authors are all people 9 that you know in your field, correct? 10 A. I've heard of their names. 11 Q. Okay. These are all widely 12 respected statisticians and 13 epidemiologists, correct? 14 MS. MILLER: Objection. 15 MR. LOCKE: Objection. 16 THE WITNESS: I -- I -- I 17 can't speak to what respect they 18 do or they do not have. I know 19 their names. 20 BY MR. TISI: 21 Q. And do you have respect for 22 them? 23 MS. MILLER: Objection. 24 THE WITNESS: The only name</p>	<p style="text-align: right;">Page 493</p> <p>1 field that depends on statistical 2 modeling." 3 Do you see that? 4 A. That's what it says there. 5 Q. Okay. So this has been 6 endorsed by 800 of your colleagues? 7 MR. LOCKE: Objection. 8 BY MR. TISI: 9 Q. Correct? 10 A. I don't know who the 800 11 people are. 12 Q. Okay. And they say, "The 13 pervasive problem" -- here on Page 1, 14 says, "Let's be clear about what must 15 stop. We should never conclude that 16 there is no difference or no association 17 just because a P-value is larger than a 18 threshold of .05, or equivalently because 19 a confidence interval includes zero. 20 "Neither should we conclude 21 that two studies conflict because one had 22 a statistically significant result and 23 the other did not. These errors waste 24 much research efforts and misinform</p>

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<p style="text-align: right;">Page 494</p> <p>1 policy decisions." 2 Do you see that? 3 A. That's what they say. 4 Q. Do you agree? 5 A. I -- I -- I don't know if I 6 agree or not. I mean, I have to read 7 this more through more carefully. There 8 are some aspects that I agree. I agree 9 that, you know, it's wrong to conclude 10 that two studies conflict because one has 11 statistically significant results or not. 12 So I agree with the example 13 that they give, null or one has a risk 14 ratio of 1.2, that it is statistically -- 15 that has -- that is statistically 16 significant, or just is not statistically 17 significant by the .05 level if P-value 18 of .091. 19 Another one also has a risk 20 ratio of 1.2, so similar risk ratios. 21 And its P-value is statistically 22 significant. So I agree that I would not 23 conclude that those two studies conflict. 24 Q. And they result -- and they</p>	<p style="text-align: right;">Page 496</p> <p>1 Q. Okay. But their statement 2 is definitive. They're not hedging at 3 all? They're saying don't do this. 4 MS. MILLER: Objection. 5 THE WITNESS: They are 6 hypothesizing. 7 BY MR. TISI: 8 Q. They are not hypothesizing. 9 They're saying let's be clear about what 10 must stop. 11 A. That, they're clear about. 12 But again, if I could -- you asked me if 13 I agree with this statement. And you cut 14 me off when I said that they are 15 hypothesizing. So may I finish that? 16 Q. Sure. 17 A. So they are hypothesizing by 18 saying eradicating -- and I'm surprised 19 statisticians are doing this. 20 "Eradicating categorization will help to 21 halt overconfident claims, unwarranted 22 declarations of no difference, and absurd 23 statements about replication failure. 24 I don't see any evidence.</p>
<p style="text-align: right;">Page 495</p> <p>1 talk about the American Statistical 2 Association in the statement that we just 3 read from 2016, right? The associated 4 statement in the American Statistician, 5 warning against the misuse of statistical 6 significance. And that was what we just 7 talked about as Exhibit Number -- 8 A. 28. 9 Q. -- 28, correct? 10 A. They cite that statement, 11 yes. 12 Q. And it says, "Eradicating 13 categorization will help halt" -- 14 A. Now where do you -- where 15 are you now? 16 Q. In the middle. In the blue. 17 A. Okay. 18 Q. "Eradicating categorization, 19 will help halt overconfident claims, 20 warranted claims of no different and 21 absurd statements about replication 22 failure." 23 Do you agree with that? 24 A. Again, I think it depends.</p>	<p style="text-align: right;">Page 497</p> <p>1 This is a hypothesis, that doing this is 2 going to stop this. I don't see any 3 evidence here, unless it's in here, which 4 I haven't been able to read in detail, 5 that there's evidence doing so is going 6 to prevent these things. 7 Q. Let's go to the next page. 8 And there's a paragraph that I want you 9 to read. I'm going to ask you to read it 10 in entirety because it deals with an 11 issue that we talked about before. 12 Go to the next page. It 13 says under the term second on the 14 left-hand side. And it says -- and I'll 15 read it into the record. 16 "Second, not all values 17 inside" -- they're talking about inside 18 the confidence interval -- are equally 19 compatible with the data, given the 20 assumptions. 21 "The point estimate is the 22 most compatible, and the values near it 23 or more compatible than those at the 24 outer" -- "near the limits. That is why</p>

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<p style="text-align: right;">Page 498</p> <p>1 we urge authors to discuss the point 2 estimate, even when we have large 3 P-values or a wide interval, as well as 4 discussing the limits of that interval. 5 "For example, authors above 6 could have written, "Like a previous 7 study our results suggest a 20 percent 8 increased risk on new onset atrial 9 fibrillation in patients given 10 antiinflammatory drugs. Nonetheless, the 11 risk difference ranging from a 3 percent 12 decrease, a small negative association, 13 to a 48 percent increase, a substantial 14 positive association, is also reasonably 15 compatible with our data. 16 "Interpreting the point 17 estimate while acknowledging its 18 uncertainty will keep you from making 19 false declarations of no difference and 20 then making overconfident claims." 21 Do you see that? 22 A. I -- that's what it says 23 there. 24 Q. Okay. Now, let's go back to</p>	<p style="text-align: right;">Page 500</p> <p>1 the number? 2 THE WITNESS: And after 3 that, and I'm willing to do this. 4 But I do need a bathroom break. 5 That water I drank. 6 Yes, I have it. 7 MR. SOILEAU: It's 26. 8 MS. MILLER: I got it. 9 THE WITNESS: We have it. 10 BY MR. TISI: 11 Q. First, we talked about -- 12 the comment that we talked about before 13 if you look at the -- the most likely, do 14 you agree with the statement in this, 15 "The point estimate is the most 16 compatible with" -- "and the values near 17 it are more compatible than those near 18 the limits in terms of the true risk." 19 A. Yeah, so can I place 20 something -- it says compatible with the 21 data. It doesn't say compatible with the 22 truth. We don't know the truth. 23 So compatible with the data, 24 I agree. Compatible with the truth, I do</p>
<p style="text-align: right;">Page 499</p> <p>1 talk about talc. First of all, do you 2 agree with that? 3 A. Again, I -- I would need to 4 read. I don't know what study they are 5 talking about above. I mean, I think 6 I -- 7 Q. Well, they're talking about 8 the one we read on the prior page, the 9 example that we read on the prior page 10 with the example that we talked about -- 11 that was talked about, that I asked you 12 to read before. 13 A. So I'm not comfortable 14 agreeing or disagreeing with something 15 that I was just handed and told, okay, 16 you have a few minutes to read through 17 this, you know, quickly and not have time 18 to think about it. So I'm just not 19 comfortable saying whether I agree or 20 not. 21 Q. Well, let's go to 22 Dr. Merlo's chart if we could, back to 23 that. 24 MS. MILLER: Do you remember</p>	<p style="text-align: right;">Page 501</p> <p>1 not agree because we don't know the 2 truth. And we're just trying to estimate 3 it with the data. But it could be 4 drastically wrong, like if there are 5 recall biases and selection biases. 6 Q. But one of the things that 7 statisticians do is they say, look at the 8 whole confidence interval, right? They 9 say, here, the real thing that you really 10 need to do is look at the range 11 represented by the confidence interval. 12 A. I think -- yeah, they're 13 just saying one should look at the 14 uncertainty in the estimate by looking at 15 the confidence interval. 16 Q. Okay. And the example they 17 give is, if the confidence interval goes 18 from a negative, and like a .97 all the 19 way up to a 1.48, that you should talk 20 about the fact that, yes, it crosses 21 zero. And you might have some risk that 22 is negative. But most of the risk lies 23 in the positive area. 24 A. Yeah, I don't know where you</p>

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<p style="text-align: right;">Page 502</p> <p>1 are getting that confidence interval. I 2 don't see a .97. 3 Q. It says here, "Nonetheless, 4 the risk difference ranging from a 3 5 percent decrease" -- 6 A. Oh, I see. 7 Q. -- "a small negative 8 association" -- 9 A. Okay. 10 Q. -- "to a 48 percent" -- "a 11 substantial" -- 12 A. I see. So you took one 13 minus 3 percent. I got it. I'm with 14 you. 15 Q. Okay. Okay. And so what 16 they're saying is you look at the 17 entirety of the confidence interval and 18 use your judgment. And you don't rely on 19 a snap decision of saying statistically 20 significant or not, true? 21 A. Say -- ask the question 22 again. 23 Q. They're saying you don't 24 just flip a switch on statistical</p>	<p style="text-align: right;">Page 504</p> <p>1 to the exhibit with Dr. Merlo's exhibit 2 there. Would you please take for me, if 3 you could -- I'm going to give you this 4 pen. And would you please highlight for 5 me every single risk ratio that's above 6 one? 7 MS. MILLER: Objection. 8 THE WITNESS: The risk ratio 9 itself? 10 BY MR. TISI: 11 Q. Yes. 12 A. I'm sorry. I goofed. 13 MS. MILLER: Can you give a 14 new one? She made a mistake. 15 THE WITNESS: Can I color it 16 in green or something so -- 17 BY MR. TISI: 18 Q. Yeah, color it -- well, why 19 don't we put an X by it. This way we'll 20 know. Which one did you do it wrong? 21 A. The last one. 22 Q. Okay. That's Gonzalez. For 23 the record, Gonzalez is not greater than 24 one, correct?</p>
<p style="text-align: right;">Page 503</p> <p>1 significance. They say you look at the 2 entirety of the confidence interval in 3 the context of everything, correct? 4 A. Yeah. They're saying one -- 5 one can report the confidence interval so 6 that you know the uncertainty that's 7 associated with the point estimate. 8 MS. MILLER: Okay. I think 9 she asked for a break. 10 MR. TISI: Sure. Although 11 we're in the -- yeah, if you need 12 to do a break, we'll do that. 13 THE WITNESS: It can only be 14 like two minutes. 15 THE VIDEOGRAPHER: All 16 right. Stand by, please. Remove 17 your microphones. The time is 18 4:48 p.m. Off the record. 19 (Short break.) 20 THE VIDEOGRAPHER: We are 21 back on the record. The time is 22 4:54 p.m. 23 BY MR. TISI: 24 Q. Doctor, if you can go back</p>	<p style="text-align: right;">Page 505</p> <p>1 MS. MILLER: Objection. 2 THE WITNESS: Yes, that's 3 correct. 4 BY MR. TISI: 5 Q. So now -- 6 A. The risk ratio. 7 Q. Now, the next thing that 8 Dr. Greenland and his colleagues point 9 out here is that we look at the 10 confidence interval, correct? 11 A. What do you mean by the next 12 thing? 13 Q. Well, one of the things he 14 says, you need to look not at statistical 15 significance so much as the confidence 16 interval, correct? 17 A. Where is that statement? 18 Q. Well, he says here, he says, 19 "The point estimate is the most 20 compatible value and the values near the 21 most comparable" -- "comparable than 22 those near the limits. That's why you 23 urge authors to discuss the point 24 estimate even when you have a large</p>

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<p style="text-align: right;">Page 506</p> <p>1 P-value or wide interval." 2 Okay. And then he talks 3 below about where the confidence interval 4 rates go, correct? 5 A. Well, you didn't quite 6 complete that sentence. So when they 7 have a large P-value or wide interval as 8 well as discussing the limits of the 9 interval. 10 Q. Okay. So let's discuss the 11 limits of the interval for a moment. 12 A. Okay. 13 Q. Okay. I'm going to ask you, 14 if you wouldn't mind, to circle every 15 P-value on -- every confidence interval 16 that includes 1.2 -- actually, let me use 17 a black pen, use that -- that includes 18 1.2 either as -- within the upper or 19 lower bounds. 20 A. Every confidence interval? 21 Q. Yeah, where 1.2 is within 22 the confidence interval. I'll ask you to 23 do one other thing. This is the last 24 thing I'll asked you to do with art.</p>	<p style="text-align: right;">Page 508</p> <p>1 numbers on the page, for most of 2 these, are greater than one. 3 BY MR. TISI: 4 Q. Okay. Would you also agree 5 that irrespective of design, every one of 6 these -- every one of these studies that 7 you highlighted in yellow, the vast 8 majority of -- excuse me, highlighted in 9 red -- 10 A. Pink. 11 Q. -- pink are consistent with 12 a 20 percent increased risk of ovarian 13 cancer? 14 MS. MILLER: Objection. 15 THE WITNESS: That I 16 disagree with. 17 BY MR. TISI: 18 Q. Okay. Why would you say 19 that? 20 A. Because we know that 21 population-based case-control studies -- 22 or, sorry, case-control studies and -- 23 well, and to some degree the cohort 24 studies have confounding and bias in</p>
<p style="text-align: right;">Page 507</p> <p>1 Take this blue pen, and 2 would ask you to put a mark by the side 3 of anything that in any of those studies 4 that include within the confidence 5 interval of 1.25? 6 MS. MILLER: Objection. 7 BY MR. TISI: 8 Q. Or maybe you can highlight 9 the inside of the -- however you want to 10 do it. It's up to you. 11 A. (Witness complies.) 12 Q. Doctor, when you were 13 looking at this, you had an opportunity 14 to take a look at this, and you've done a 15 little bit of art here on this. 16 Irrespective of the 17 statistically -- statistical 18 significance, would you agree that, 19 irrespective of design, every one of 20 these studies that -- the vast majority 21 of them, have a point estimate greater 22 than one? 23 MS. MILLER: Objection. 24 THE WITNESS: I mean, the</p>	<p style="text-align: right;">Page 509</p> <p>1 these. 2 And so, therefore, it's hard 3 to know what the true risk ratio is, 4 because if you're consistently 5 overestimating something, just because 6 every study that has the same design that 7 consistently overestimates something, 8 doesn't make the truth. That's something 9 that is estimated. 10 Q. Let me put it this way. 11 Would you agree with me with respect to 12 the cohort studies and the case-control 13 studies, that the vast majority of them 14 have in common a 20 percent -- have 15 20 percent in their confidence interval? 16 MS. MILLER: Objection. 17 THE WITNESS: I don't know 18 why that would be relevant, 19 because as what you were just 20 having me read before, it says 21 look at the risk ratios and see 22 sort of if they're the same. Like 23 the example they gave, they had 24 two risk ratios which were exactly</p>

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<p>1 the same. One was statistically 2 significant, one was not. 3 And as I pointed out in my 4 report, the risk ratios across the 5 case-control studies differ by as 6 much as four times. And so -- 7 BY MR. TISI: 8 Q. Do you really expect in any 9 set of studies in anything that you've 10 ever done, that the risk ratios be 11 exactly the same? 12 A. To be exactly the same? 13 Again, it depends upon the studies that 14 I'm comparing. 15 Q. In fact, wouldn't you be 16 suspicious of a set of studies of any 17 design which had exactly the same risk 18 ratio? 19 MS. MILLER: Objection. 20 THE WITNESS: Again, I would 21 have to see -- it depends on what 22 the studies are that I'm looking 23 at and so forth. 24 BY MR. TISI:</p>	<p>1 this. Because I want to get kind of -- 2 isn't the decision -- the vast majority 3 of these studies have a risk ratio 4 between 1.1 -- irrespective of design, 5 1.1 and 1.5. Would you agree with that? 6 There is some outliers on the low end and 7 outliers on the high end. But the vast 8 majority of them. 9 A. But your -- so your -- 10 your -- your -- 11 Q. Go ahead. 12 A. So when I look at numbers, I 13 can say that those numbers fall in that 14 range. 15 As to whether or not the 16 true risk ratio is in that range, I have 17 no idea, because I know of the biases 18 that exist, especially in the 19 case-control studies. 20 Q. Now, didn't Dr. -- have you 21 calculated a confounding -- how big a 22 confounder would have to be in order to 23 create a risk ratio of 1.3? 24 A. I think it depends. It</p>
Page 511	Page 513
<p>1 Q. Have you ever seen that 2 happen, a group of five studies where 3 they all have exact same risk ratio? 4 MS. MILLER: Objection. 5 THE WITNESS: The exact 6 same -- I mean, to how many 7 decimal places? I've seen studies 8 that -- yeah. 9 BY MR. TISI: 10 Q. Where five studies done in 11 different populations, have the exact 12 same risk ratio. 13 MS. MILLER: Objection. 14 BY MR. TISI: 15 Q. You've seen that happen? 16 A. Again, I -- I don't know. I 17 mean, I -- it depends upon what level you 18 are measuring at, is the same. If one 19 would say, oh, look, you know, all these 20 have a risk ratio of one because someone 21 rounded 1.2 down to one, 1.1 down to one, 22 then, yes, that study could have all the 23 same. 24 Q. So, Doctor, let me ask you</p>	<p>1 depends upon many factors. 2 Q. Well, how big would it have 3 to be? 4 A. I can't answer that because 5 I need to know many things in order to 6 calculate that. 7 Q. If you go back to Dr. 8 Rothman's Exhibit Number -- this one, the 9 one that looks like this. 10 MR. SOILEAU: It should be 11 21. 12 BY MR. TISI: 13 Q. 21. 14 A. Yes, I have it. 15 Q. Okay. Here's a section in 16 here, a paragraph on confounding in the 17 case-control studies, on Page 5. 18 Do you see that? 19 A. Yes, I see that paragraph. 20 Q. Okay. Can you read that 21 paragraph? You can read it to yourself. 22 A. You know, I see that -- 23 Q. I just asked you to read it. 24 There's no question pending.</p>

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<p>1 A. Okay. Okay, sorry. Yes, I 2 read that. 3 Q. Okay. Does he not say that, 4 "Family history, ethnicity, obesity and 5 some reproductive risk factors are 6 positively associated with the risk of 7 ovarian cancer"? 8 A. Yes. 9 Q. He says, even if you combine 10 all of those together, they would not 11 explain increased risk? 12 A. You know, he states that 13 there, but I would need to see the 14 calculation. I don't see any 15 calculation. So I don't know if that 16 statement is correct or not. 17 Q. Well, have you done the 18 calculations that would say that -- how 19 big the confounding would have to be in 20 order to explain the consistent risks 21 seen across all these case-control 22 studies? 23 MS. MILLER: Objection. 24 THE WITNESS: I have not</p>	<p>1 get it? 2 THE WITNESS: That would be 3 great. That's the one with the 4 douching? 5 MS. MILLER: Sure. Let's go 6 off the record, and I'll get it. 7 THE VIDEOGRAPHER: The time 8 is 5:09 p.m. Off the record. 9 (Brief pause.) 10 THE VIDEOGRAPHER: The time 11 is 5:11 p.m. Back on the record. 12 BY MR. TISI: 13 Q. Okay. So let me turn to 14 dose-response, which is another area you 15 spend a lot of time on. And I'm going to 16 spend rest of my time on dose-response, 17 which is another of Hill's criteria. 18 First of all, do you agree 19 with me that Bradford Hill said himself 20 that dose-response was not a required 21 finding in order to make a causation 22 assessment, correct? 23 A. I believe Bradford Hill 24 indicates that none of these are -- are a</p>
Page 515	Page 517
<p>1 done that calculation, but I don't 2 see a calculation here either. 3 BY MR. TISI: 4 Q. I'm not asking you. He's -- 5 he made his assertion. You're here, I'm 6 getting to ask you questions. You've 7 made a big deal about confounding in your 8 report. A big deal. 9 I'm asking you, have you 10 made any calculation as to how big the 11 confounder would have to be to explain 12 what the meta-analysis show as 13 approximately 1.3 risk associated with 14 ovarian cancer and talc? 15 MS. MILLER: Objection. 16 THE WITNESS: Again, I -- I 17 have not made such a calculation, 18 but -- can I see -- is it the 19 Gonzalez study? 20 BY MR. TISI: 21 Q. Did you bring it with you? 22 MS. MILLER: I've got all 23 the studies in the next room. Do 24 you want to go off the record and</p>	<p>1 requirement to establish causation, and I 2 agree with that. 3 Q. Okay. The next -- the next 4 statement on page -- turn to Page 19 of 5 your report. On Page 19, you say -- and 6 it's your general discussion of 7 dose-response. 8 Do you see that? 9 A. Under biological -- 10 Q. No. Above -- above 11 plausible -- yes, under -- above 12 plausibility. 13 A. Oh, so we're on 19. 14 Q. Yes. 15 A. Okay. 16 Q. You talk about biologic 17 gradient. You start out by saying it's 18 not necessary. And the next -- but the 19 next paragraph is what I'm going to ask 20 you about. 21 A. I dent see where I say it's 22 not necessary. 23 Q. Okay. 24 A. I see that I see if</p>

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<p style="text-align: right;">Page 518</p> <p>1 dose-response is seen, it's more likely 2 the association is causal. 3 Q. Okay. So let's go to the 4 next paragraph. It says, "Regardless of 5 the nature of the dose-response 6 relationship, it needs to be demonstrated 7 consistently across available studies. 8 Specifically the same type of 9 dose-response relationship needs to be 10 exhibited in the different studies. If a 11 threshold relationship is hypothesized, 12 it would require evidence of a threshold 13 value as well, and the value is similar 14 across studies. 15 "If only a few studies 16 exhibit a dose-response rather than all, 17 this criterion" -- "criterion would not 18 be convincingly met." 19 I'm going to have that 20 marked as Exhibit Number 36 (sic). I 21 just pulled that paragraph out. 22 (Document marked for 23 identification as Exhibit 24 Ballman-30.)</p>	<p style="text-align: right;">Page 520</p> <p>1 A. I give citations for that. 2 So you're going to have to bear with me. 3 And I will find -- 4 So 30 and 31. "Hence, 5 observational studies that yield small to 6 modest levels of association require a 7 higher level of supporting evidence to 8 reach a conclusion of causality than do 9 studies with strong levels of 10 association." 11 Q. Okay. So if I look at 30 12 and 31, references to those will be in 13 there? 14 A. That will support that 15 statement. Mm-hmm. 16 Q. Okay. I'll look them up. 17 So now let's go -- let's go 18 to the next -- let's go to exhibit 19 number -- the exhibit that I just gave 20 you, the pull-out of your report. 21 We agreed that, okay -- 22 where is your statement that 23 dose-response needs to be demonstrated 24 consistently across the available</p>
<p style="text-align: right;">Page 519</p> <p>1 BY MR. TISI: 2 Q. First of all, you would 3 agree with me -- would you agree with me 4 that you have not cited a single 5 reference for any of those statements? 6 A. I just think it's common 7 knowledge in terms of the general 8 principles of epidemiology for 9 establishing a dose-response. 10 Q. So where is your -- I'm 11 going to hand you Exhibit Number 30. I'm 12 going ask you about the highlighted ones. 13 Where is your authority 14 for -- in fact, you had indicated that 15 dose-response wasn't even necessary 16 according to Bradford Hill, right? You 17 agreed with that? 18 A. Qualified. I would say -- 19 and I state throughout my report, that if 20 the initial association that's 21 established is weak then it's important 22 that other criteria be met. 23 Q. And where is your basis for 24 that?</p>	<p style="text-align: right;">Page 521</p> <p>1 studies? 2 A. Well, I think I'm sort of 3 explaining what I mean by consistently. 4 I mean, if one study out of 40 had a 5 dose-response, that likely is just due to 6 the fact of multiple comparisons. So 7 that would not establish a dose-response. 8 So dose-response is very 9 similar to establishing whether -- I 10 mean, consistency is sort of implied in 11 terms of dose-response. You can't have 12 one study showing a dose-response out of 13 many and conclude there is a 14 dose-response. 15 Q. Okay. Actually -- I'm 16 actually asking you this. 17 Regardless of the nature of 18 the dose-response, it needs to be 19 demonstrated consistently across the 20 available studies. Where is your support 21 for that statement that it needs to be 22 consistent across all -- across available 23 studies? 24 A. So just -- just common sense</p>

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<p style="text-align: right;">Page 522</p> <p>1 off the top of my head, but I can go 2 through and try to find references if 3 you'd like. 4 But if something is causal, 5 it would be quite odd that it would only 6 have a dose-response in, say, one out of 7 40 studies. And again, I think I 8 explained that in my previous answer. 9 Q. The next sentence says, 10 "Specifically, the same type of 11 dose-response relationship needs to be 12 exhibited in the different studies." 13 Could you -- you have no 14 citation for that, right? 15 A. Again, if something is 16 causal, it would be odd that in one 17 study, it's a threshold effect, and in 18 another study it's a sign effect, and yet 19 in another study it's a decreasing 20 effect, and in another study it's an 21 increasing effect. What would you 22 conclude? How could you conclude it to 23 be causal? 24 Q. Well, it depends on what you</p>	<p style="text-align: right;">Page 524</p> <p>1 nine years .9. Ten to 19 is 1.4. 2 Greater than 20, it's .9. 3 So that's going up and down. 4 Q. Can I stop and ask you that 5 question? Do you know how many people 6 were in the last category? 7 A. No. I have no idea how many 8 people were in the last category. But 9 the width of the confidence intervals 10 there look like it's relatively close to 11 perhaps what's in the previous 12 categories. 13 Q. Okay. Let me ask you 14 another question here. On the next 15 sentence? 16 A. Wait -- I can show you one 17 where -- Whittemore, it goes down. It's 18 1.9, it's 1.6, and greater than ten years 19 it's 1.1. 20 Q. Is that -- is that 21 never/ever? What is that? 22 A. That's duration. 23 Q. Okay. So wouldn't the best 24 measurement be frequency?</p>
<p style="text-align: right;">Page 523</p> <p>1 measure, correct? It depends on the 2 power of the study. It depends upon a 3 lot of things, right? 4 A. Dose-response looks for 5 patterns. I'm not even talking 6 statistically significant here. So 7 things that you just mentioned are 8 talking about statistical significance, 9 which you say people are going to 10 abandoned in the future. 11 I'm talking about looking 12 for evidence that supports a 13 dose-response. And if you have one study 14 that it shows it's going up and down, 15 another study that it's going down, 16 another study that even if it's not 17 statistically significant, that would 18 raise red flags. 19 Q. What study, what study 20 showed that it was going down? Would 21 that be the Huncharek study? 22 A. I can tell you in a minute. 23 Wong? So -- well, here's one that's up 24 and down. So Wong, one point -- one to</p>	<p style="text-align: right;">Page 525</p> <p>1 MS. MILLER: Objection. 2 BY MR. TISI: 3 Q. Or total number -- total 4 number of applications? 5 MS. MILLER: I assume my 6 objection applies to the second 7 question. 8 MR. TISI: Yes, it would. 9 BY MR. TISI: 10 Q. Wouldn't the total -- 11 MS. MILLER: That was the 12 second question. 13 BY MR. TISI: 14 Q. Wouldn't -- 15 MS. MILLER: Those are two 16 different things. 17 MR. TISI: I got it. I got 18 it. 19 BY MR. TISI: 20 Q. Wouldn't the total -- 21 wouldn't the best measure be the total 22 number of applications? 23 A. Well, if we're getting into 24 measurements, first of all, there's no</p>

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<p style="text-align: right;">Page 526</p> <p>1 valid instrument as to how to best 2 measure talc exposure. So having no 3 valid instrument in the first place, I 4 don't think one can say what's the best 5 measure for a dose-response. If 6 something is truly causal and you are 7 measuring increasing dose with some 8 metric that has increasing, so duration 9 would be increasing, that, you know, the 10 longer you use, the more likely you would 11 get ovarian cancer. 12 Frequency would be also a 13 measure of dose-response because using it 14 once a week is, you know, much less than 15 using it every day. And so they are all 16 some measures of dose-response. 17 So if there's a true causal 18 relationship, one would expect seeing 19 consistent sort of dose-responses across 20 any of those measures. 21 Q. And the Terry study did show 22 that, didn't it, when you combine 23 frequency and duration, correct? 24 A. Well, that -- it -- it looks</p>	<p style="text-align: right;">Page 528</p> <p>1 if you do five studies would you expect 2 the same relative risk. 3 And, you know, these all 4 could be sort of the same underlying 5 relative risk and just come up with the 6 variations, because the numbers don't 7 differ that much. So it's sort of a flat 8 relationship. 9 Q. This is -- this is a 10 meta-analysis, isn't it? This is looking 11 at all studies together? 12 A. Yeah, I don't know if that 13 makes it any stronger or not because, 14 again, there's no valid measure that was 15 used. So combining a bunch of studies 16 that use a bunch of different measures 17 together and no valid measure of talc 18 exposure in general, and then no, you 19 know, valid measure as to what the total 20 applications were or consistent 21 standardized measure, you know, it's hard 22 to interpret -- 23 Q. And Penninkilampi -- 24 A. -- the pooled --</p>
<p style="text-align: right;">Page 527</p> <p>1 like -- do we have the Terry study? 2 Q. I'm just asking -- you have 3 the results in your -- in your Table 3. 4 A. Oh, in Table 3. Thank you. 5 Q. Mm-hmm. 6 A. Yeah, I see it now. Thanks. 7 I thought it was here. You know, I -- 8 I -- I actually gave it the benefit of 9 the doubt because there's a couple issues 10 here. One needs to -- so the test for 11 trend is not statistically significant. 12 And if you look at this, you 13 see that it goes from 1.14 to 1.23 down 14 to 1.22 and then up to 1.32. So I don't 15 know if I'd call that a -- 16 Q. So you're kind of quibbling 17 with the Q3 going down from 1.23 to 1.22, 18 as showing, oops, it dropped a tenth of 19 the point? 20 A. Well, I'm quibbling that -- 21 actually if you look at, you know, the 22 last three values there, you know, it 23 well may be the case that there are 24 really -- as you were pointing out, that</p>	<p style="text-align: right;">Page 529</p> <p>1 Q. I'm sorry. I didn't mean to 2 interrupt you. 3 A. Sorry. It's just hard to 4 interpret a pooled study. 5 Q. And Penninkilampi also 6 looked at less than 3,600 applications 7 and more than 3,600 applications, and 8 there was a difference there as well, 9 right? 10 A. And, again, if a test for a 11 trend were done the correct way where you 12 do not have the never category in, it's 13 likely that that would not be a 14 statistically significant difference. 15 But that aside, looking at these point 16 estimates, those again could probably 17 happen -- it doesn't indicate sort of a 18 clear difference between those two 19 numbers -- 20 Q. How about Schildkraut? 21 A. -- and those point 22 estimates. 23 Q. In your study -- in your 24 chart, on the prior page, on Table 1,</p>

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<p style="text-align: right;">Page 530</p> <p>1 Schildkraut shows less than 3,600, had a 2 1.16, and at greater than 3,600 had a 3 1.67, to a P-value of .01. 4 A. That's not really -- that's 5 not really a test for dose-response 6 because there's only two levels. So it's 7 sort of like just comparing two levels to 8 each other. You don't know for certain. 9 Q. So -- so let me go back to 10 your statement. It says Exhibit 11 Number -- exhibit right there, what 12 number -- what exhibit? 13 A. 30. 14 Q. Exhibit 30. Last sentence 15 says, "If only a few studies exhibit 16 dose-response rather than all, the 17 criterion would not be convincingly met." 18 First of all, you have no 19 citation for that either, do you? 20 MS. MILLER: Objection. 21 THE WITNESS: Other than 22 what we discussed before, because 23 if there's true causality, it 24 would be quite odd that only,</p>	<p style="text-align: right;">Page 532</p> <p>1 this criterion more important. 2 And you say that those 3 two -- there's no citation here. But you 4 gave me the citation to that concept 5 earlier, right? 6 A. I did. 7 Q. Okay. The next paragraph 8 says, "To establish a dose-response 9 relationship, the necessary evidence is 10 increasing risk with increasing dose, 11 statistical significance, and 12 consistency. Consistency in this context 13 includes repeated demonstration of the 14 result across different studies, 15 including different study designs and 16 different measures of dose." 17 Do you see that? 18 A. Mm-hmm. 19 Q. And I have that pulled out 20 here as well as Exhibit Number -- 21 (Document marked for 22 identification as Exhibit 23 Ballman-31.) 24 BY MR. TISI:</p>
<p style="text-align: right;">Page 531</p> <p>1 like, two studies show any sort of 2 dose-response relationship and the 3 rest do not. 4 And you know, we can do the 5 counting exercise and go through 6 and see of all these, these 7 different measures of 8 dose-response, how many of them 9 actually are potentially. And I 10 don't even know if I would call 11 the highlighted ones showing a 12 dose-response relationship. 13 BY MR. TISI: 14 Q. Let's go to the next -- Page 15 29 of your report. You say -- on Page 16 29, you say, "Given" -- sorry. Let me 17 see where I find it. Where is the word 18 "given"? Hold on. 19 Oh, okay. On the first 20 paragraph you say -- second sentence, you 21 say, "Given that available data are from 22 observational data and the association is 23 weak, additional evidence is required to 24 rule out a spurious association making</p>	<p style="text-align: right;">Page 533</p> <p>1 Q. As with the prior statement, 2 you don't have a single citation for that 3 do you? 4 A. I think we discussed all 5 this before in Exhibit 30 about why 6 consistency is important. And why the 7 same type of dose-response needs to be 8 important. I think I -- 9 Q. But you didn't cite it 10 there, and you don't cite it here? 11 MS. MILLER: Objection. 12 BY MR. TISI: 13 Q. You didn't cite it in the 14 prior exhibit, and you don't cite 15 anything here. 16 MS. MILLER: Sorry. I 17 thought the last thing was a 18 question, so I objected to that. 19 But this is a new question. I 20 object to this one as well. 21 BY MR. TISI: 22 Q. Yeah. Okay. We looked at 23 two -- 24 A. Yeah, yeah, yeah, yeah.</p>

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<p style="text-align: right;">Page 534</p> <p>1 Q. -- Exhibit Number 30, and 2 Exhibit Number 31. They're both the same 3 statement about consistency, and you 4 don't have a citation for either one of 5 those? 6 A. And I explained why there is 7 no citation is, again, that if there is a 8 causal relationship that is in fact true, 9 one would expect to see the same type of 10 relationship because if it goes up in one 11 study, down in another, up and down, or 12 stays flat, it's hard to understand how 13 something that truly has a causal effect 14 would come up with these different sort 15 of dose-responses. 16 And again, consistency is, 17 again, that you don't have these 18 different patterns going on in the data. 19 Q. But you have no citation for 20 that whatsoever, and the meta-analyses 21 that were done, the two of them that 22 looked at it, whether it be Terry -- or 23 you pointed out. I'm blanking on the 24 other one. Both showed evident of a</p>	<p style="text-align: right;">Page 536</p> <p>1 even know if there's any valid measure of 2 that. 3 Q. But you would agree with me 4 that both of these are peer-reviewed 5 studies, and when you looked at the total 6 number of applications, which is a 7 measure of dose, we saw an increased 8 risk. Whether you think it's the right 9 inference or not is fine, but you agree 10 with that -- that that's what they 11 showed, both Penninkilampi and Terry. 12 And that's on Page 34 of your report. 13 A. I don't think I said that. 14 I think I said Penninkilampi, you can't 15 even infer dose-response because there's 16 only two doses. It's only two lines. So 17 you can't -- I mean, only like -- you 18 know, dichotomous things. 19 So one can't really infer a 20 dose-response, and it's not even clear 21 that those two numbers in reality differ 22 from each other because we had this 23 discussion about, you know, point 24 estimates, you know, not having -- that</p>
<p style="text-align: right;">Page 535</p> <p>1 dose-response -- Terry and 2 Penninkilampi -- that looked at total 3 number of -- those are the only two that 4 looked at the total number of 5 applications, and they both showed 6 increasing dose -- increasing risk with 7 increasing number of applications, true? 8 A. That is -- again, there's no 9 evidence that that's the right metric 10 because there's no validated instrument 11 for measuring talc in the first place. 12 And so it's sort of cherry-picking to 13 say, oh, okay, that one shows it but a 14 measure of frequency doesn't show it, a 15 measure of duration doesn't show it, even 16 within the same studies. 17 And so I think most 18 reasonable people would say, if there 19 really is a dose-response, why does it 20 have to be sort of the total lifetime 21 applications, but I'm not seeing it in 22 the total of years, which goes into that 23 calculation, nor the frequency, which 24 goes into that calculation. And I don't</p>	<p style="text-align: right;">Page 537</p> <p>1 they don't have to be the same, and if 2 they are pretty close to each other, who 3 knows. 4 So that's the same with the 5 Terry study too. So I do not agree. 6 Q. Okay. But different -- you 7 know that in those studies, that both of 8 them, they noted an evidence of 9 dose-response, correct? 10 MS. MILLER: Objection. 11 THE WITNESS: I would have 12 to see the studies and see exactly 13 how they stated their conclusions. 14 Can you -- 15 BY MR. TISI: 16 Q. I'm just -- I'm just asking 17 you, do you recall that that was the 18 case? 19 A. Off the -- 20 MS. MILLER: Objection. 21 MR. LOCKE: Objection. 22 BY MR. TISI: 23 Q. I'm asking you, do you 24 recall or not? If you don't recall,</p>

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<p style="text-align: right;">Page 538</p> <p>1 that's fine. 2 A. Off the top of my head, I do 3 not recall. 4 Q. Okay. I want to ask you a 5 couple questions about meta-analysis and 6 kind of move on from there. 7 First of all, not all 8 dose-responses are monotonic, are they? 9 MS. MILLER: Objection. 10 THE WITNESS: I believe -- 11 there can be different type of 12 dose-responses. 13 BY MR. TISI: 14 Q. Okay. Have you considered 15 that? 16 A. In what sense? 17 Q. Have you considered it at 18 all? 19 MS. MILLER: Objection. 20 THE WITNESS: I think I -- 21 just in -- I mean, in what sense? 22 BY MR. TISI: 23 Q. In connection with 24 dose-response?</p>	<p style="text-align: right;">Page 540</p> <p>1 BY MR. TISI: 2 Q. In any of the studies. 3 A. Well, I know it looks like 4 Terry did a test for trend that does not 5 include the never/none category. And 6 it's P-value is .17. So -- and that is a 7 flat relationship. 8 Checking to see. 9 So Cramer 1999 did the 10 correct test. He did a trend test. And 11 his P-value of .48 and .16, that's a 12 trend test that does not include the 13 never category. 14 Q. Right, but when he looked at 15 the total number of applications, you saw 16 an increase that went from 1.1 to 1.38, 17 went down to 1.36, and up to 1.49. 18 A. I think we're talking about 19 the different Cramer. Sorry. 20 Q. Cramer 2016? 21 A. No. I was looking -- I said 22 Cramer 1999. I'm sorry. 23 Q. I'm looking -- 24 A. I misspoke that.</p>
<p style="text-align: right;">Page 539</p> <p>1 A. Well, in cancer it would be 2 very rare -- in a non-monotonic, one 3 would be that the higher the dose, the 4 less the risk. It could be concave. I 5 mean, that would be quite -- 6 Q. Could it -- 7 A. -- bizarre different from 8 any other cancers I've seen. 9 Q. Have you ever heard 10 depletion of the susceptibles? 11 A. No, I have not. 12 Q. Okay. That as people die, 13 they're not going to be showing a -- 14 anyway. I'll move on. 15 What about a trend test 16 when -- when the trend test was used in 17 non-users, did they show a dose-response? 18 MS. MILLER: Objection. 19 BY MR. TISI: 20 Q. When a trend test was used, 21 did it show a dose-response? 22 MS. MILLER: Well, where? 23 THE WITNESS: Trend test 24 used where, meaning what?</p>	<p style="text-align: right;">Page 541</p> <p>1 You asked me which ones did 2 the correct trend test. And I'm saying 3 Cramer 1999. 4 Q. What about Cramer 2016? 5 MS. MILLER: You didn't 6 misspeak. You said 1999. 7 BY MR. TISI: 8 Q. What about Cramer 2016? 9 A. That one does -- that test 10 for trend includes the never versus none 11 category. 12 Q. All right. Okay. Let me 13 ask you a couple questions about -- about 14 meta-analyses. 15 We've been talking about the 16 individual studies. Is it your view 17 that -- you know, you mentioned several 18 times. 19 MR. TISI: I'm sorry. I'm 20 sorry. You reached over. You 21 reached over that time. 22 MS. MILLER: I'm moving 23 back. 24 MR. TISI: You reached over</p>

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<p style="text-align: right;">Page 542</p> <p>1 that time.</p> <p>2 MS. MILLER: I'm so sorry.</p> <p>3 MR. TISI: And you kicked</p> <p>4 me.</p> <p>5 MS. MILLER: I'm so sorry.</p> <p>6 MR. TISI: And I don't take</p> <p>7 it personally.</p> <p>8 MS. SHARKO: Can I do that</p> <p>9 too.</p> <p>10 MS. MILLER: I had to</p> <p>11 stretch my legs. It's been a very</p> <p>12 long day. I can only stretch that</p> <p>13 far.</p> <p>14 BY MR. TISI:</p> <p>15 Q. Doctor, you mentioned</p> <p>16 several times that a certain number of</p> <p>17 case-control studies found a</p> <p>18 statistically significant result, and a</p> <p>19 certain found -- didn't. And then a</p> <p>20 certain number of case -- cohort studies</p> <p>21 did not find a statistically significant</p> <p>22 result.</p> <p>23 Do you remember that kind of</p> <p>24 general testimony?</p>	<p style="text-align: right;">Page 544</p> <p>1 not.</p> <p>2 Looking at the cohort</p> <p>3 studies, none of them found a</p> <p>4 statistically significant</p> <p>5 association.</p> <p>6 And the magnitude of the</p> <p>7 risk ratios for these groups of</p> <p>8 studies also vary.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Would you agree with me that</p> <p>11 it is wrong to simply count the number</p> <p>12 of -- count the number of studies and</p> <p>13 kind of do it like a democracy. There</p> <p>14 are a certain number of studies that say</p> <p>15 X that's not statistically significant.</p> <p>16 Certain number that say Y, they are, and</p> <p>17 the non-statistical numbers win?</p> <p>18 A. It depends.</p> <p>19 Q. Okay. Do you ever do that?</p> <p>20 A. It depends. I mean, again,</p> <p>21 I -- it depends upon many things.</p> <p>22 You know, if I have, like,</p> <p>23 you know, randomized controlled trials,</p> <p>24 you know, and, you know, all of them show</p>
<p style="text-align: right;">Page 543</p> <p>1 MS. MILLER: Objection.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Yeah, I mean. Yes?</p> <p>4 A. What's your question?</p> <p>5 Q. My question is do you</p> <p>6 remember that testimony. I'm kind of</p> <p>7 referring you. Remember you listed,</p> <p>8 well, you know, you kind of looked at</p> <p>9 them together. And some were</p> <p>10 statistically significant, some weren't.</p> <p>11 Some were in case-control, some were in</p> <p>12 cohort. Do you remember that testimony?</p> <p>13 MS. MILLER: Objection.</p> <p>14 MR. TISI: You can object.</p> <p>15 THE WITNESS: So what I --</p> <p>16 what I -- I recall sort of when</p> <p>17 looking at the evidence in</p> <p>18 totality is that you know, the --</p> <p>19 the hospital-based controls did</p> <p>20 not find statistical significance.</p> <p>21 The population-based</p> <p>22 controlled studies -- case-control</p> <p>23 studies, some found a statistical</p> <p>24 significant association, some did</p>	<p style="text-align: right;">Page 545</p> <p>1 an effect, and then or none of them show</p> <p>2 an effect, let's say. So I have</p> <p>3 randomized control trials --</p> <p>4 Q. But that's not what we're</p> <p>5 talking about. We're not talking about</p> <p>6 randomized controlled.</p> <p>7 Let's just talk about, for</p> <p>8 example, in the case-control studies.</p> <p>9 A. You asked me if there are</p> <p>10 any situations, and I was trying to</p> <p>11 answer that.</p> <p>12 Q. And we're not talking about</p> <p>13 that. And I apologize, because we're</p> <p>14 talking about in the context of this</p> <p>15 case. There are no randomized control</p> <p>16 trials because it would be unethical to</p> <p>17 do so, correct?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: Again, I</p> <p>20 talked about reasons why, you</p> <p>21 know, randomized control studies</p> <p>22 are not done and, you know --</p> <p>23 yeah, so anyway.</p> <p>24 BY MR. TISI:</p>

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<p>1 Q. They could not be done here 2 because you can't test somebody -- 3 assuming you can even design such a 4 study, you couldn't -- with the 5 hypothesis being, let's expose people to 6 something and see whether it causes 7 cancer? 8 MS. MILLER: Objection. 9 BY MR. TISI: 10 Q. It would be unethical to do 11 that, right? 12 A. Yeah. I mean, just in 13 general, one would not do a clinical 14 trial and say, okay, we're going to 15 expose people to something that there's 16 evidence for that it's harmful, but I 17 don't know if it applies in this case. 18 It's been purported that the 19 use of talc is harmful. But I don't know 20 if there is -- 21 Q. Would you ever participate 22 in a study that would test the hypothesis 23 that talc would cause ovarian cancer? 24 MS. MILLER: Objection.</p>	<p>1 done, and the intent for 2 meta-analyses is that the 3 randomized controlled trials, back 4 when trials were starting to 5 become popular, were too small on 6 their own to have statistical 7 significance. 8 So the idea was there were 9 several trials done in the same 10 disease, essentially, of the same 11 treatments, and so to get the 12 necessary power in order to make a 13 definitive statement, 14 meta-analyses were used. 15 MR. TISI: Okay. 16 (Document marked for 17 identification as Exhibit 18 Ballman-32.) 19 BY MR. TISI: 20 Q. Let me show you a textbook, 21 a chapter of a textbook called 22 "Introduction to Meta-Analyses" by 23 Borenstein. Is that something that 24 you've ever seen before?</p>
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<p>1 BY MR. TISI: 2 Q. A clinical trial? 3 MS. MILLER: Objection. 4 THE WITNESS: Again, I don't 5 think people would do such a 6 clinical trial -- 7 BY MR. TISI: 8 Q. And you wouldn't -- 9 A. -- with that question. 10 I mean, I would participate 11 in one if it says talc would prevent sort 12 of this from happening because I would 13 see a benefit. I wouldn't participate in 14 a trial where there's no benefit being 15 hypothesized. 16 Q. So now the question is, why 17 do we do meta-analysis? Why do we do 18 meta-analysis? 19 MS. MILLER: Objection. 20 THE WITNESS: Well, 21 meta-analysis, and the history of 22 meta-analysis are that they were 23 first used for randomized 24 controlled trials. And they were</p>	<p>1 A. I haven't seen this 2 particular textbook. 3 Q. I'm marking it as Exhibit 4 Number 32? And I pulled out -- 5 MS. MILLER: Is this Xerox 6 on cardboard? 7 MR. TISI: I know. The 8 machine, it was weird. It was the 9 FedEx office. 10 BY MR. TISI: 11 Q. Chapter 28 is called "Vote 12 Counting, a New Name For an Old Problem." 13 Do you see that? 14 A. I'm sorry. What page are we 15 on? 16 Q. It's chapter 28. If you go 17 in, there's the chapter there? 18 A. Oh, I see. It says "Vote 19 Counting, a New Name For an Old Problem." 20 Yes. 21 Q. So just -- you would agree 22 with me just looking at the number of 23 studies that show statistically 24 significant results and the numbers that</p>

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<p style="text-align: right;">Page 550</p> <p>1 don't is not a good scientific 2 methodology, correct? 3 A. Again, it depends. 4 Q. Well, at the very end of in 5 statement -- and I guess that was a 6 pretty non-controversial thing, at least 7 I thought it was. At the very end, 8 there's a box that says "Summary Points" 9 on Page 255. 10 I'm going to ask you if this 11 is true. "Vote counting" -- and by vote 12 counting, I mean counting the number of 13 positive and negative studies. "Vote 14 counting is the process of counting the 15 number of studies that are not (sic) 16 statistically significant and comparing 17 those with the number that are not 18 statistically significant." 19 Do you see that? 20 A. Yes, I see what you read. 21 Q. And it says, "Vote counting 22 treats a nonsignificant P-value as 23 evidence that an effect is absent. In 24 fact, though small, moderate, and even</p>	<p style="text-align: right;">Page 552</p> <p>1 studies being combined -- again, as I 2 mentioned the intent of a meta-analyses 3 was for randomized clinical trials. And 4 it was to combine small, underpowered 5 studies together in order to get 6 sufficient power. 7 Q. Do you agree that it is 8 appropriate to use meta-analysis to 9 combine observational studies, even 10 observational studies of different 11 design? 12 A. No. I think it is incorrect 13 to do a meta-analyses to combine 14 observational studies, especially 15 observational studies of different 16 designs. 17 Q. Yet in the talc area, you 18 know of at least four, five or six 19 meta-analyses that have been done that 20 have done exactly that, that have passed 21 peer review, correct? 22 A. Yeah, and I hope ASA comes 23 out with a statement on that, because the 24 intent of meta-analyses was not to</p>
<p style="text-align: right;">Page 551</p> <p>1 large effects may yield nonsignificant 2 P-values due to inadequate statistical 3 power. Therefore, vote counting is never 4 a valid approach." 5 A. Yes, I see that -- that 6 stated there. 7 Q. Do you agree that vote 8 counting -- in other words, counting the 9 number of studies that are not 10 statistically significant and comparing 11 them with the numbers that are, is never 12 a valid approach? 13 A. Again, I said it depends. 14 So if all the studies were of the same 15 sample size done in the same population 16 using the same treatment, and all of them 17 were adequately powered, and, like, two 18 only found a statistically significant 19 result, and the rest did not, I think 20 that's evidence right there that there 21 really is no effect. 22 Q. And that -- that's why we do 23 meta-analyses, correct? 24 A. We do meta-analyses when the</p>	<p style="text-align: right;">Page 553</p> <p>1 combine observational studies. And 2 that's why in the meta-analyses, in that 3 chart of increasing evidence that I -- 4 I -- we had discussed previously in my 5 report, the meta-analyses at the top are 6 meta-analyses of randomized trials. I've 7 never seen any pyramid of evidence of 8 that that puts in meta-analyses of 9 observational studies anywhere in that 10 pyramid because it's unknown. 11 Q. But I'm -- let me just get 12 it down. There are six meta-analyses in 13 this -- in this litigation, five which 14 have been published, one of which is 15 being submitted to peer review, right, 16 the Taher study. 17 A. Yes, correct. 18 Q. And there's -- there's six 19 altogether, five of which are 20 published -- 21 A. Oh, wait? Six altogether. 22 No, I'm sorry. Go through the numbers 23 again. My count is seven published. 24 Q. Okay. Fine.</p>

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<p>1 A. And -- okay.</p> <p>2 Q. Fine. Whatever the number</p> <p>3 happens to be, it happens to be. I'm</p> <p>4 doing it off the top of my head.</p> <p>5 Are you saying that because</p> <p>6 all of those studies combined</p> <p>7 observational studies -- let's just deal</p> <p>8 with that issue -- that that was</p> <p>9 unscientific, and they should not have</p> <p>10 passed peer review?</p> <p>11 A. I am saying that they're</p> <p>12 good for hypothesis generating, and</p> <p>13 that's about it. They are not good for</p> <p>14 making definitive statements with respect</p> <p>15 to things such as causality or whether</p> <p>16 there truly is an association.</p> <p>17 Q. Do you think that those</p> <p>18 should have passed peer review. If you</p> <p>19 were peer reviewers on any of the</p> <p>20 meta-analyses that are in this case,</p> <p>21 would you have given a green light to</p> <p>22 allow those to be published?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: Again, they</p>	<p>1 meta-analyses of observational</p> <p>2 data.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Okay. And you think it</p> <p>5 would be inappropriate to rely on that</p> <p>6 data for consideration in the -- of the</p> <p>7 Bradford Hill criteria for causation in</p> <p>8 talc and ovarian cancer?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: As I said,</p> <p>11 meta-analyses are good for</p> <p>12 hypothesis generating, but they</p> <p>13 are not sufficient evidence to --</p> <p>14 to make a definitive statement</p> <p>15 about causation.</p> <p>16 BY MR. TISI:</p> <p>17 Q. I didn't ask about</p> <p>18 definitive statements. I'm asking, are</p> <p>19 they even appropriate to consider in a</p> <p>20 Bradford Hill analysis, or is that a</p> <p>21 methodologic flaw if anybody were to</p> <p>22 consider a meta-analysis in the context</p> <p>23 of doing a Bradford Hill test or analysis</p> <p>24 for ovarian cancer and talc?</p>
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<p>1 are good for hypothesis</p> <p>2 generating. And I didn't say that</p> <p>3 hypothesis generating is not --</p> <p>4 not good -- or is not -- I'm</p> <p>5 getting tired. I'm searching for</p> <p>6 words here.</p> <p>7 I did not say that</p> <p>8 hypothesis generating should not</p> <p>9 be published.</p> <p>10 BY MR. TISI:</p> <p>11 Q. You would agree with me that</p> <p>12 people disagree with you on the value of</p> <p>13 meta-analyses, correct?</p> <p>14 MS. MILLER: Objection.</p> <p>15 THE WITNESS: Well, I -- I</p> <p>16 don't know. All I know is JCO,</p> <p>17 the journal I'm deputy editor for,</p> <p>18 which has quite a high impact</p> <p>19 factor, we would never, ever</p> <p>20 publish a meta-analyses -- well, I</p> <p>21 shouldn't say that. That's too</p> <p>22 strong.</p> <p>23 It would be very rare that</p> <p>24 we ever would publish a</p>	<p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: As I -- I do</p> <p>3 cite one of the articles here that</p> <p>4 says -- I don't -- within Bradford</p> <p>5 Hill, it says look at the totality</p> <p>6 of the data. But it's more</p> <p>7 important to look at the</p> <p>8 individual studies and see what</p> <p>9 the conclusion comes from there,</p> <p>10 rather than a meta-analyses.</p> <p>11 So I'm not sure how a</p> <p>12 meta-analyses sort of plays into</p> <p>13 the Bradford Hill except coming up</p> <p>14 with some summary values.</p> <p>15 BY MR. TISI:</p> <p>16 Q. But you do know that most</p> <p>17 people looking at this question have</p> <p>18 looked at -- at the meta-analyses,</p> <p>19 correct, in connection -- I mean, Health</p> <p>20 Canada did, correct? Are they wrong for</p> <p>21 having done so?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I didn't say</p> <p>24 that. I mean, I said even I've</p>

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<p>1 looked at the meta-analyses 2 because that's the totality of the 3 data, to see if there's any sort 4 of additional information that it 5 brings forward. 6 BY MR. TISI: 7 Q. But do you remember the 8 statement -- and I pulled it out there. 9 I think it was Exhibit Number 5. That 10 statement says that they found a 11 consistent result across meta-analyses 12 and additional evidence is consistent 13 with causation. 14 MS. MILLER: Who is "they"? 15 MR. TISI: Health Canada. 16 THE WITNESS: I'm trying to 17 find Exhibit 5. 18 MR. LOCKE: Can I ask for a 19 time check? 20 MR. TISI: We've got about 21 four minutes. 22 THE WITNESS: I'm looking 23 for Exhibit 5. Do you have it 24 handy? Oh, I got it. I got it.</p>	<p>1 MS. MILLER: Objection. 2 THE WITNESS: And I said 3 that when one is doing a proper 4 sort of causal analyses that's 5 based upon, you know, established 6 epidemiology principles, one looks 7 at all studies, including 8 meta-analyses. 9 BY MR. TISI: 10 Q. Are they wrong for having 11 relied on them? Having looked at them, 12 can they rely on them? 13 MS. MILLER: Objection. 14 THE WITNESS: I'm not sure 15 if they relied on them from this 16 statement here. I can't tell that 17 they relied just on meta-analyses 18 or not. 19 BY MR. TISI: 20 Q. What is the journal JCO? 21 A. The Journal of Clinical 22 Oncology. 23 Q. One final question. You 24 made a comment in the Taher study that</p>
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<p>1 I got it. Okay. 2 BY MR. TISI: 3 Q. Were they wrong -- were 4 Health Canada wrong in Exhibit 5 for 5 relying on that? 6 A. So I think I said that 7 meta-analyses, it's not surprising that 8 they are consistent because they are 9 analyzing the same set of data, and so 10 one would expect -- 11 Q. I didn't ask you that. I 12 didn't ask you about consistency. I'm 13 asking were they wrong for even 14 considering them? 15 A. But that's a different 16 question -- 17 Q. It is a different question. 18 A. -- than what you just asked 19 me there. 20 Q. I'm asking you, are they 21 wrong for having considered them in the 22 context of looking at the causal 23 inference for talcum powder and ovarian 24 cancer?</p>	<p>1 they indicated that they thought it was a 2 possible association. And you said that 3 you thought that as a peer reviewer, they 4 would take that out? 5 A. No. They said a possible 6 causal -- 7 Q. Causal association. 8 A. -- association. 9 Q. And you would take -- you 10 thought that that was something that 11 would be taken out by peer reviewers, 12 correct? 13 A. Of -- of high quality 14 journals, yes. 15 Q. And you -- but that's pure 16 speculation on your part, right? 17 A. No, I do not believe so. 18 Through all my experience in the numerous 19 papers that I've reviewed and -- both for 20 JCO and as a reviewer of other things, 21 that's pushing the data, because one 22 assumes no causal relationship, and you 23 need evidence for it before you can state 24 causality.</p>

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<p style="text-align: right;">Page 562</p> <p>1 Q. Would it surprise you to 2 know that we have meta-analyses in JCO, 3 correct? Would that surprise you? You 4 mentioned that you've never published 5 meta-analyses or rarely. Would that 6 surprise you? 7 A. There are meta-analyses -- 8 MS. MILLER: Objection. She 9 said meta-analyses -- objection. 10 THE WITNESS: There are 11 meta-analyses in JCO of randomized 12 clinical trials. And in fact, one 13 of the studies you showed me today 14 was a meta-analysis. It was a 15 pooled analysis, of individual 16 patient-level data. 17 BY MR. TISI: 18 Q. Okay. So is it your 19 statement that JCO would not publish a 20 meta-analyses -- meta-analysis of 21 observational data? 22 MS. MILLER: Objection. 23 Misstates -- 24 THE WITNESS: I said it</p>	<p style="text-align: right;">Page 564</p> <p>1 minute. 2 MR. TISI: I'm totally okay. 3 I'll give you -- I'll give you my 4 minute. 5 Thank you very much. I have 6 no further questions. 7 MS. MILLER: I just have a 8 few questions for you, Dr. 9 Ballman. 10 - - - 11 EXAMINATION 12 - - - 13 BY MS. MILLER: 14 Q. Can you please turn back to 15 Exhibit Number 25. 16 MR. TISI: Which is what? 17 THE WITNESS: The National 18 Cancer Institute one. This one? 19 BY MS. MILLER: 20 Q. Can you tell me what the 21 title of that exhibit is? 22 A. The title is "Ovarian, 23 Fallopian Tube, and Primary Peritoneal 24 Cancer" -- I don't know if there's</p>
<p style="text-align: right;">Page 563</p> <p>1 was -- 2 MS. MILLER: 3 Mischaracterizes her testimony. 4 Please let me finish my 5 objection, even though you're 6 eager to talk. 7 BY MR. TISI: 8 Q. You can answer the question. 9 A. Okay. So I said that it 10 would very rarely happen. I had 11 corrected. I had said never, but I said, 12 no, wait a minute, it would very rarely 13 happen. 14 Q. Okay. So -- so you would 15 agree with me that there have been 16 observational meta-analyses in JCO? 17 A. I have no idea if there have 18 been or not. I cannot say that off the 19 top of my head. 20 MR. TISI: I don't think I 21 have any questions. I think I'm 22 down to the -- 23 MS. MILLER: You have one 24 minute. Go crazy with your last</p>	<p style="text-align: right;">Page 565</p> <p>1 anything under the sticker -- 2 "Prevention, Health Professional 3 Version." 4 Q. And what is this document? 5 A. It's a document that was 6 published by the National Cancer 7 Institute that's talking about who's at 8 risk for ovarian cancer and established 9 risk factors of ovarian cancer, I 10 believe, as best I can tell. 11 Q. Please turn to Page 11. 12 A. Yes, I'm there. 13 Q. Do you see the subheading 14 titled "Perineal Talc Exposure"? 15 A. Oh, yes, I see "Perineal 16 Talc Exposure." Yes. 17 Q. Can you please read the 18 sentence under that? 19 A. "The weight" -- 20 Q. You did a lot of reading 21 today. I thought we should you read, 22 too. 23 A. "The weight of evidence does 24 not support an association between</p>

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<p>1 perineal talc exposure and an increased 2 risk of ovarian cancer." 3 Q. Did Mr. Tisi read this 4 sentence to you? 5 A. No. And it goes on to say 6 that the result from case-control and 7 cohort studies are inconsistent. 8 MS. MILLER: I have no 9 further questions. 10 MR. TISI: I have a 11 question. I'll use my minute and 12 add a couple minutes to yours. 13 MS. MILLER: Wait. I used 14 30 seconds. So you have a minute 15 and 30 seconds. 16 MR. TISI: Okay. Well don't 17 waste my 30 seconds. I don't 18 think I'll use 30 seconds. 19 - - - 20 EXAMINATION 21 - - - 22 BY MR. TISI: 23 Q. In that section, it 24 refers -- there are four footnotes under</p>	<p>1 references for the values that 2 they're reporting before the 3 reference -- 4 BY MR. TISI: 5 Q. So if you go to the back -- 6 A. -- such as, "However, a 7 dose-response relationship was not 8 found," which is reference 42. 9 Q. Can you look at Page 16 of 10 18. 11 MS. SHARKO: I really think 12 your time is up at this point. 13 MS. MILLER: Yeah, your time 14 is way up. 15 THE WITNESS: I'm there. 16 MS. MILLER: You've just 17 gone over two more minutes. 18 MR. TISI: Counsel, you've 19 been wasting my time. I'm going 20 to ask this question. And if you 21 want to -- you want to walk out, 22 that's fine. I'll ask the judge 23 for the time. 24 BY MR. TISI:</p>
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<p>1 the perineal talc section. 2 Do you see that? 3 A. Yeah, I'm sorry. I thought 4 I was done. 5 Q. On -- on Page 12. Footnote 6 43 through footnote 46. 7 Do you see that? 8 A. I see -- I see Reference 42 9 and I see a reference 43. I don't see 10 where you see -- oh, there's 44. Yeah, I 11 see -- I see a bunch of -- 12 Q. And 46? 13 A. 44, 45, 46. 14 Q. Right. So there are five 15 references in this paragraph, correct? 16 A. Yes. 17 Q. Okay. And so we can assume, 18 can we not, that those are the references 19 they looked at? 20 MS. MILLER: Objection. 21 Calls for speculation. 22 THE WITNESS: I don't know 23 if it's all the references that 24 they looked at. I think they are</p>	<p>1 Q. How many -- how many 2 references -- of all these references, 3 there are five references. Do you have 4 any -- any suggestion that the NCI 5 actually did a causation analysis like 6 you or Health Canada or the plaintiffs' 7 experts or anybody else did? 8 MS. MILLER: Objection. 9 THE WITNESS: I don't know. 10 I don't know what they did. 11 MR. TISI: Thank you very 12 much. 13 THE VIDEOGRAPHER: Stand by, 14 please. Remove your microphones. 15 The time is 5:54 p.m. This 16 completes today's deposition. 17 (Excused.) 18 (Deposition concluded at 19 approximately 5:54 p.m.) 20 21 22 23 24</p>

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<p>1 2 CERTIFICATE 3 4 5 I HEREBY CERTIFY that the 6 witness was duly sworn by me and that the 7 deposition is a true record of the 8 testimony given by the witness. 9 10 It was requested before 11 completion of the deposition that the 12 witness, KARLA BALLMAN, Ph.D., have the 13 opportunity to read and sign the 14 deposition transcript. 15 16 MICHELLE L. GRAY, 17 A Registered Professional 18 Reporter, Certified Shorthand 19 Reporter, Certified Realtime 20 Reporter and Notary Public 21 Dated: March 24, 2019 22 23 (The foregoing certification 24 of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)</p>	<p>1 - - - - - 2 E R R A T A 3 - - - - - 4 PAGE LINE CHANGE 5 6 REASON: _____ 7 8 REASON: _____ 9 10 REASON: _____ 11 12 REASON: _____ 13 14 REASON: _____ 15 16 REASON: _____ 17 18 REASON: _____ 19 20 REASON: _____ 21 22 REASON: _____ 23 24 REASON: _____</p>
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<p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition 4 over carefully and make any necessary 5 corrections. You should state the reason 6 in the appropriate space on the errata 7 sheet for any corrections that are made. 8 After doing so, please sign 9 the errata sheet and date it. 10 You are signing same subject 11 to the changes you have noted on the 12 errata sheet, which will be attached to 13 your deposition. 14 It is imperative that you 15 return the original errata sheet to the 16 deposing attorney within thirty (30) days 17 of receipt of the deposition transcript 18 by you. If you fail to do so, the 19 deposition transcript may be deemed to be 20 accurate and may be used in court. 21 22 23 24</p>	<p>1 2 ACKNOWLEDGMENT OF DEPONENT 3 4 I, _____, do 5 hereby certify that I have read the 6 foregoing pages, 1 - 574, and that the 7 same is a correct transcription of the 8 answers given by me to the questions 9 therein propounded, except for the 10 corrections or changes in form or 11 substance, if any, noted in the attached 12 Errata Sheet. 13 14 15 16 KARLA BALLMAN, Ph.D. DATE 17 18 19 Subscribed and sworn 20 to before me this 21 _____ day of _____, 20____. 22 My commission expires: _____ 23 24 Notary Public</p>

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